

US3322353 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:06:27

All time stamps listed in this document are displayed in GMT

US3322353

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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Participant ID

US3322353

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

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US3322353

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Date of Informed Consent ( <i>dd MMM yyyy</i> )	15 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) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

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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) 26 Feb 2021 04:06:00

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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) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	IRRITABLE BOWEL SYNDROME
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)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	INTERNAL HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	HIATAL HERNIA SURGERY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	INDIRECT INGUINAL HERNIA SURGERY
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	INTERNAL HEMORRHOID LIGATION PROCEDURE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	HEARING AIDS
Start date (dd MMM yyyy)	UN MAR 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)	MAR 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) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	PEDAL EDEMA
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 (11)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Condition	ELEVATION OF PROSTATE-SPECIFIC ANTIGEN
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)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:50 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 14:50
Height ( <i>xxx.x</i> )	75 in
Weight ( <i>xxx.x</i> )	200 lb
BMI ( <i>xxx.x</i> )	25.05056 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) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 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) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

### Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

Specify

CONTRACTOR INTERACTING  
WITH 6-10 PEOPLE /DAY.  
WORKS >3 DAYS /WK

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

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 04:06:00

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	True
<b>Specify</b>	GROCERY SHOPPING 1/ WEEK . GOES TO GYM 3 TIMES / WEEK . LIVES WITH HIS WIFE WHO HAS OCCUPATION REQUIRING CLOSE OR FREQUENT CONTACT WITH PEOPLE ( REALTOR )

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

What was the date of randomization? (dd MMM yyyy) 15 SEP 2020

What was the participant's randomization number? 190610

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) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

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)	15 SEP 2020
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 15:01
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	17:18 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 17:18
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 22:09:45

Generated On: 09 Jun 2021 17:06:27

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) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 16:33 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 16:33

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

16:01 (24 HR)

Collection date and time (derived)

15 SEP 2020 16:01

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:54	15 SEP 2020 15:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:06:00

Generated On: 09 Jun 2021 17:06:27

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: 09 Jun 2021 17:06:27

**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

96.5 °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

15 SEP 2020 17:12

PC Open Date & Time

15 SEP 2020 16:53

PC Close Date & Time

15 SEP 2020 19:23

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.5 °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	16 SEP 2020 09:33
PC Open Date & Time	15 SEP 2020 20:18
PC Close Date & Time	16 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 15:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 17:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

18 SEP 2020 15:06

---

PC Open Date & Time

18 SEP 2020 12:00

---

PC Close Date & Time

19 SEP 2020 11:59

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US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 14:51

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 13:30

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 13:20

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**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

15 SEP 2020 17:14

PC Open Date & Time

15 SEP 2020 16:53

PC Close Date & Time

15 SEP 2020 19:23

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 09:34

PC Open Date & Time

15 SEP 2020 20:18

PC Close Date & Time

16 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**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

16 SEP 2020 15:31

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**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

17 SEP 2020 17:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**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

18 SEP 2020 15:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**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

19 SEP 2020 14:51

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**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

20 SEP 2020 13:30

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**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

21 SEP 2020 13:21

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**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 ☐

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 17:15
PC Open Date & Time	15 SEP 2020 16:53
PC Close Date & Time	15 SEP 2020 19:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**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 ☐

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 09:35
PC Open Date & Time	15 SEP 2020 20:18
PC Close Date & Time	16 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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 ☒

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EAB) (1725)



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 15:31
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**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 ☒

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:19
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2299

EAB) (1725)

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 15:07
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2299

EAB) (1725)

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 14:52
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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 ☐



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 13:31
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**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

65 of 2299

EAB) (1725)

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 13:21
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3322353

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

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

Visit date (dd MMM yyyy)	13 OCT 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:09
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:40
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3322353

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

13 OCT 2020

---

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

---

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 OCT 2020

What was the treatment time? (00:00-23:59) 14:03 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 14:03

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

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

13:55 (24 HR)

Collection date and time (derived)

13 OCT 2020 13:55

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	13 OCT 2020 13:50
Nasopharyngeal Swab 2	No		



US3322353

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 14:40

PC Open Date & Time

13 OCT 2020 14:23

PC Close Date & Time

13 OCT 2020 16:53

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp 13 OCT 2020 18:47

PC Open Date & Time 13 OCT 2020 17:48

PC Close Date & Time 14 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 13:02

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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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

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

15 OCT 2020 14:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

16 OCT 2020 16:18

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 17:49

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 16:36

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 13:39

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 14:41

PC Open Date & Time

13 OCT 2020 14:23

PC Close Date & Time

13 OCT 2020 16:53

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 18:45

PC Open Date & Time

13 OCT 2020 17:48

PC Close Date & Time

14 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 13:02

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**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

15 OCT 2020 14:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 16:18

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 17:49

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 16:36

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59



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Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 13:39

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**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 ☐

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 14:41
PC Open Date & Time	13 OCT 2020 14:23
PC Close Date & Time	13 OCT 2020 16:53

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**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 ☐

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 18:46
PC Open Date & Time	13 OCT 2020 17:48
PC Close Date & Time	14 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 13:03
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 14:16
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**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 ☒

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 16:18
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 17:50
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 16:36
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 13:39
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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



US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 12:05
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322353

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 NOV 2020

Collection time (00:00-23:59)

13:07 (24 HR)

Collection date and time (derived)

10 NOV 2020 13:07

US3322353

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:06:01

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 12:47:18

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 12:44:46
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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

26 NOV 2020 12:02:20

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

<b>TIMEPOINT</b>	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 15:17:22
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59



US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 12:01:35

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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	17 DEC 2020 12:13:21
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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

24 DEC 2020 17:16:12

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 13:16:33
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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	07 JAN 2021 09:17:39
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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	14 JAN 2021 10:14:04
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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

21 JAN 2021 14:09:50

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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

28 JAN 2021 08:30:52

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59



US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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

05 FEB 2021 10:40:16

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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

11 FEB 2021 13:53:18

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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

18 FEB 2021 15:54:07

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 08:45:58

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 17:41:52

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 21:27:09

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 19:06:17
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 14:16:46

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59



US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 10:10:23

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 19:51:07

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 10:22:17

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 16:45:03

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 11:19:27

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

---

10 MAY 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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°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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	20 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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°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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	27 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	10 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	17 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	01 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	22 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	29 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	23 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	20 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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°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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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°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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	17 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 FEB 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	16 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	23 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 <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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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15 AUG 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	01 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	20 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	27 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**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°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 ☐

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	10 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2022 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

17 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

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US3322353

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:06:27

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 13:09:00



US3322353

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:58

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:09:45

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322353

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:09:45

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322353

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 23:59:50

Generated On: 09 Jun 2021 17:06:27

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

Visit date (dd MMM yyyy)	30 MAR 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	VISIT4
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US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 23:59:50

Generated On: 09 Jun 2021 17:06:27

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) \_\_\_\_\_

US3322353

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 23:59:50

Generated On: 09 Jun 2021 17:06:27

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.*

US3322353

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 23:59:50

Generated On: 09 Jun 2021 17:06:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	14:23 (24 HR)
Collection date and time (derived)	30 MAR 2021 14:23

US3322353

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 23:59:50

Generated On: 09 Jun 2021 17:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

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

Comments

*If Contact Not Made, please provide Comments*

**US3322353**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:27**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322353

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:27

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"/>



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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:06:27

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3322353

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

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

Visit date (dd MMM yyyy)	26 JAN 2021
--------------------------	-------------

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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US3322353

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 22:09:45

Generated On: 09 Jun 2021 17:06:27

Date of updated informed consent (dd MMM yyyy) 26 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 26 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3322353

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

12:51 (24 HR)

Collection date and time (derived)

26 JAN 2021 12:51

US3322353

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	12:46
Collection Date and Time (derived)	26 JAN 2021 12:46

US3322353

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

AEID	USA-US060-2020-MRNA-1273-P30 1000007
Adverse event	PROSTATE ADENOCARCINOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 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)	08 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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"/>

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US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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



US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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SUBJECT CALLED OUR SITE ON  
27 OCT 2020 TO LET US KNOW  
THAT ON FRIDAY 23 OCT 2020  
HE FOUND OUT THAT HE HAS  
PROSTATE CANCER. BIOPSY OF  
PROSTATE WAS ON 16 OCT 2020  
THUS START DATE WAS  
CHANGED. PATIENT  
PRESENTED FOR UROLOGY  
FOLLOW-UP S/P ROBOTIC  
ASSISTED PROSTATECTOMY,  
BILATERAL PELVIC LYMPH  
NODE DISSECTION,  
NEUROPLASTY, BLADDER  
SUSPENSION ON 06JAN2021.  
PATIENT HAD SURGERY ON  
08DEC2020 (EVENT END DATE).  
PATIENT'S HOSPITAL STAY  
UNCOMPLICATED AND  
WITHOUT INCIDENT. PATIENT  
DISCHARGED FROM HOSPITAL  
IN STABLE CONDITION ON  
09DEC2020. PATIENT IS  
RECOVERING WELL; HAS BEEN  
REFERRED FOR PELVIC FLOOR  
PHYSICAL THERAPY DUE TO  
URINARY INCONTINENCE.  
PATIENT ALSO HAS  
CONTINUING ERECTILE  
DYSFUNCTION AND IS USING A  
VACUUM ERECTION DEVICE  
(VED). CT OF ABDOMEN/PELVIC  
AND BONE SCAN NEGATIVE  
FOR METASTATIC DISEASE ON  
NOV 2020. GRADING: PT3B N1

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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(1/7) R0 GG 5 PROSTATE CA.  
ONE LYMPH NODE NOTED TO  
BE POSITIVE, WILL AWAIT  
REPEAT PSA TO DETERMINE  
NEXT STEPS, POSSIBLY  
RADIATION. PSA ON 06JAN2021  
<0.02 (REFERENCE RANGE <0.10  
AFTER RADICAL  
PROSTATECTOMY). AT  
PRESENT, MEDICAL  
CONDITION IS STABILIZED  
AND RESOLVED WITH  
SEQUELAE. NEXT FOLLOW UP  
FOR SURVEILLANCE  
SCHEDULED FOR APRIL 2021.  
PATIENT IS CLINICALLY  
STABLE AT PRESENT AND WILL  
CONTINUE WITH CANCER  
SURVEILLANCE PER  
UROLOGIST'S  
RECOMMENDATIONS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

---

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US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

AEID	
Adverse event	GASTROESOPHAGEAL REFLUX DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 NOV 2020
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"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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 <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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

AEID

Adverse event

LOWER URINARY TRACT  
SYMPTOMS

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)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 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 (3)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

AEID	
Adverse event	COLONIC DIVERTICULOSIS
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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 checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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	True
Concomitant Medication	False
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)	



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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

AEID	
Adverse event	BLADDER DIVERTICULA
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)	25 SEP 2020
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 checked="" type="radio"/> Grade 2/Moderate <input 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 (5)

Data signed: (b) (4) 26 Feb 2021 04:05:45

Generated On: 09 Jun 2021 17:06:27

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	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

---

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

Yes ☒

No ☐

---

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

---

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

Name of Medication TESTOSTERONE CYPIONATE

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 10 DAYS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1987	
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"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

Name of Medication FINASTERIDE

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATIC  
HYPERPLASIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2014	
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 (3)

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Name of Medication ALFUZOSIN

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATIC  
HYPERPLASIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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	Intraocular	<input type="radio"/>
	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)	UN UNK 2014	
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) 15 Apr 2021 19:32:52

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Name of Medication TRIAMTERENE

Prophylaxis Yes ☐  
No ☒

Indication PEDAL EDEMA

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 (4)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	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 MAY 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 (5)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	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 1975	
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 (6)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

Name of Medication FOLIC ACID

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	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 1985
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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Name of Medication PSYLLIUM FIBER SUPPLEMENT

Prophylaxis Yes ☐  
No ☒

Indication IRRITABLE BOWEL SYNDROME

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	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 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 (8)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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Name of Medication IMODIUM

Prophylaxis Yes ☐  
No ☒

Indication IRRITABLE BOWEL SYNDROME

Dose per administration 1/2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 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 (10)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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Name of Medication DESMOPRESSIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY INCONTINENCE

Dose per administration 0.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONE TABLET 2-3 TIMES A WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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	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)		6 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)		_____
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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Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 NOV 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 (12)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication LOWER URINARY TRACT SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 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)		02 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐  
No ☒

Indication LOWER URINARY TRACT SYMPTOMS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 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)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 19:32:52

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Name of Medication SILDENAFIL

Prophylaxis Yes ☐  
No ☒

Indication PULMONARY HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	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)		19 NOV 2019
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"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	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 1998	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 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"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

Name of Medication GENTAMICIN SULFATE

Prophylaxis Yes ☐  
No ☒

Indication LOWER URINARY TRACT SYMPTOMS

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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)	29 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)		29 SEP 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"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS OF INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 19:32:52

Generated On: 09 Jun 2021 17:06:27

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 NOV 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"/>

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 16:35:11

Generated On: 09 Jun 2021 17:06:27

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 OCT 2020	PROSTATE BIOPSY	Diagnostic	
25 SEP 2020	PROSTATE MAGNETIC RESONANCE IMAGING WITH OR WITH OUT CONTRAST	Diagnostic	
08 DEC 2020	ROBOTIC ASSISTED PROSTATECTOMY, BILATERAL PELVIC LYMPH NODE DISSECTION, NEUROPLASTY, BLADDER SUSPENSION	Medical History	
UN NOV 2020	COMPUTERIZED TOMOGRAPHY (CT) OF ABDOMEN/PELVIS	Diagnostic	
UN NOV 2020	BONE SCAN	Diagnostic	
UN NOV 2020	VACUUM ERECTION DEVICE	Medical History	

US3322353

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:27

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3322353

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:27

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 ☐

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/OCT/2020 13:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/DEC/2020 15:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/FEB/2021 12:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Feb 2021 04:05:46

Generated On: 09 Jun 2021 17:06:27

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/FEB/2021 16:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3322353 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

**US3322353**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:06:27**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:24:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'US3322353'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:14:15

US3322353

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:27



US3322353

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:14:17

US3322353

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Clinic (Clinic)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:27

US3322353

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'SCRN'	System	15 Sep 2020 21:42:27

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:14:18

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '73'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

**US3322353**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:27**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'YEARS'	System	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '73'	System	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Male (M)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28



US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'l'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28



US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:27

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:06:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Sep 2020'	System	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2020'	System	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Amendment 3 (3)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55



US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:14:17

US3322353

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'I'	System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:08:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:06:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:09:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:37

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
Data point term sent to Coder	System	15 Sep 2020 21:44:30
User entered 'Irritable Bowel syndrome'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 2015'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55



US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2015'	System	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2015'	System	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:43:55



US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Internal hemorrhoids - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
Data point term sent to Coder	System	15 Sep 2020 21:44:32
User entered 'internal Hemorrhoids'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 2016'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2016'	System	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2016'	System	15 Sep 2020 21:44:05



US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Sep 2020 21:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
Data point term sent to Coder	System	15 Sep 2020 21:44:32
User entered 'benign prostatic hyperplasia'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 1990'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24



US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 1990'	System	15 Sep 2020 21:44:24

**US3322353**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '1990'	System	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Reproductive system and breast disorders, HLT: 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)	15 Sep 2020 21:46:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:46:50
Data point term sent to Coder	System	15 Sep 2020 21:45:35
User entered 'Erectile Dysfunction'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 1984'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36



US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 1984'	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '1984'	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Diaphragmatic therapeutic procedures, PT: Hernia hiatus repair, LLT: Hiatal hernia repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Sep 2020 21:46:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:46:50
Data point term sent to Coder	System	15 Sep 2020 21:45:35
User entered 'Hiatal Hernia surgery'	Frances Saubon (b) (4)	15 Sep 2020 21:45:03
	(b) (4)	

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 1995'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03



US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 1995'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 1995'	System	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '1995'	System	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 1995'	System	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '1995'	System	15 Sep 2020 21:45:03



US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 06:13:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:13:53
Data point term sent to Coder	System	15 Sep 2020 21:46:36
User entered 'indirect inguinal Hernia surgery'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 1997'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 1997'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 1997'	System	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '1997'	System	15 Sep 2020 21:45:56



US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 1997'	System	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '1997'	System	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoid ligation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 06:12:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:12:50
Data point term sent to Coder	System	15 Sep 2020 21:46:36
User entered 'internal hemorrhoid ligation procedure'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 2018'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 2018'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13



US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoid ligation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 06:12:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:12:50
Data point term sent to Coder	System	15 Sep 2020 21:46:36
User entered 'internal hemorrhoid ligation procedure'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 2019'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29



US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN UNK 2019'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Hearing aid user, LLT: Hearing aid user - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Sep 2020 21:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:48:53
Data point term sent to Coder	System	15 Sep 2020 21:47:39
User entered 'Hearing Aids'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'UN Mar 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43



US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Mar 2020'	System	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2020'	System	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	15 Sep 2020 21:46:43



US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Pedal edema - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:53:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:53:04
Data point term sent to Coder	System	30 Oct 2020 21:52:05
User entered 'pedal edema'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'un UNK 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:12:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2020'	System	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2020'	System	30 Oct 2020 21:51:26



US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:53:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:53:04
Data point term sent to Coder	System	30 Oct 2020 21:52:05
User entered 'urinary incontinence'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'un UNK 2018'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:13:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49



US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2018'	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2018'	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:21:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Investigations, HLT: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: Prostate specific antigen increased - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Nov 2020 23:46:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:46:44
Data point term sent to Coder	System	10 Nov 2020 21:16:28
User entered 'elevation of prostate-specific antigen'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:21:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'un UNK 2015'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:21:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:21:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28



US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:21:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:21:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2015'	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2015'	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy prostate normal, LLT: Prostatic biopsy normal - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Nov 2020 06:07:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:07:45
Data point term sent to Coder	System	10 Nov 2020 21:16:27
User entered 'prostatic biopsy for hyperplasia - negative'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'un UNK 2015'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46



US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'un UNK 2015'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2015'	System	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2015'	System	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2015'	System	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2015'	System	10 Nov 2020 21:15:46



US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary hypertension, PT: Pulmonary hypertension, LLT: Pulmonary hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Nov 2020 22:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:47:44
Data point term sent to Coder	System	10 Nov 2020 22:46:33
User entered 'pulmonary hypertension'	(b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'Jan 2019'	System	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '2019'	System	10 Nov 2020 22:46:16



US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '14:50'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '15 Sep 2020 14:50'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '75' in	(b) (4)	
	Frances Saubon (b) (4)	15 Sep 2020 21:47:54
DataPoint set to visible.	(b) (4)	
	System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '200' lb	(b) (4) Frances Saubon (b) (4)	15 Sep 2020 21:47:54
DataPoint set to visible.	(b) (4) System	15 Sep 2020 21:42:00



US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '25.05056'	System	15 Sep 2020 21:47:54
DataPoint set to visible.	System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'kg/m2'	System	15 Sep 2020 21:47:54
DataPoint set to visible.	System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'bpm'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54



US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'breaths/min'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'mmHg'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'mmHg'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14

US3322353

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:00



US3322353

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:00

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40



US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'contractor interacting with 6-10 people /day. Works >3 days /wk'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	Frances Saubon (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40



US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'I'	Frances Saubon (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:24:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'grocery shopping 1/ week	(b) (4)	
. Goes to Gym 3 times / week	Frances Saubon (b) (4)	15 Sep 2020 21:48:40
. Lives with his wife who has occupation requiring	(b) (4)	
close or frequent contact with people ( realtor )'		

US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:25:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:49:25

US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:25:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Sep 2020 13:49:44
User entered '15 Sep 2020' reason for change: Data Entry Error	System	17 Sep 2020 13:49:44
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	Elisa Moralez (b) (4)	17 Sep 2020 13:49:44
User entered '16 Sep 2020'	(b) (4)	
	System	17 Sep 2020 13:49:25
	Elisa Moralez (b) (4)	17 Sep 2020 13:49:25
	(b) (4)	



US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[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 06:59:51
DataPoint Verified.		04 Mar 2021 19:25:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:49:25

US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'VISIT1'	System	17 Sep 2020 13:49:25

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
	System	17 Sep 2020 13:49:44
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 13:49:44
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:49:25
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:44:28

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '190610'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:44:28

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:44:28

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

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 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

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 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:27

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:31:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	27 Sep 2020 02:48:15
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:17:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:17:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
	System	17 Sep 2020 13:51:22
User entered '15 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	17 Sep 2020 13:51:22
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:12
User entered '16 Sep 2020'	Elisa Moralez (b) (4)	17 Sep 2020 13:51:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
	System	17 Sep 2020 13:51:22
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:12
User entered '15:01'	Elisa Moralez (b) (4)	17 Sep 2020 13:51:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered '15 Sep 2020 15:01'	System	17 Sep 2020 13:51:22
User entered '16 Sep 2020 15:01'	System	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '97.7' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '62'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'bpm'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'breaths/min'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '137'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '89'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	17 Sep 2020 13:51:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:31
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	17 Sep 2020 13:51:12
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	System	17 Sep 2020 13:51:31
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Elisa Moralez (b) (4)	17 Sep 2020 13:51:31
User entered '16 Sep 2020'	(b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '17:18'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered '15 Sep 2020 17:18'	System	17 Sep 2020 13:51:31
User entered '16 Sep 2020 17:18'	System	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 12:50:38
User closed query 'Per CDM: Site response noted; however, please confirm if the PI considers the event to be CS or NCS. Refer to CCGs for more details. Thank you. ' (Site from DM).		21 Sep 2020 06:43:32
Query 'Per CDM: Site response noted; however, please confirm if the PI considers the event to be CS or NCS. Refer to CCGs for more details. Thank you. ' answered with 'NCS' (Site from DM).	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 21:49:42
User opened query 'Per CDM: Site response noted; however, please confirm if the PI considers the event to be CS or NCS. Refer to CCGs for more details. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:31:45
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PER SOURCE' (Site from System).	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:51
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 13:51:12
User entered '96.5' F	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '56'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'bpm'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'breaths/min'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '155'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:35:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '83'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12



US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:10:10
User closed query 'Per CCG if screening and day one are same day physical is capture under screening and no should be selected under day 1. Please confirm and update accordingly.' (Site from CRA).		23 Mar 2021 03:10:01
Query 'Per CCG if screening and day one are same day physical is capture under screening and no should be selected under day 1. Please confirm and update accordingly.' answered with 'updated, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:19:51
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:19:43
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:19:43
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:19:43
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:36:21
User opened query 'Per CCG if screening and day one are same day physical is capture under screening and no should be selected under day 1. Please confirm and update accordingly.' (Site from CRA).		04 Mar 2021 19:36:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:23

US3322353

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:10:20
DataPoint Un-verified.	Elisa Moralez (b) (4)	09 Mar 2021 22:19:43
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 22:19:43
User entered empty; reason for change Data Entry Error	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 22:19:43
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:36:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15 Sep 2020'	(b) (4) Elisa Moralez (b) (4)	17 Sep 2020 13:52:23

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:36:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:36:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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 06:59:51
DataPoint Verified.		04 Mar 2021 19:36:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:36:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	17 Sep 2020 13:49:44
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 13:49:44
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:49:25
User entered '15 Sep 2020'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14



US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:36:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '16:33'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered '15 Sep 2020 16:33'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:36:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:36:42
User entered 'ONCE'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:40

US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:40

US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '16:01'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:40



US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered '15 Sep 2020 16:01'	System	17 Sep 2020 13:52:40

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15:54'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered '15 Sep 2020 15:54'	System	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50



US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered empty.	System	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:54

US3322353

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered '1'	System	17 Sep 2020 13:52:54

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12'	System	15 Sep 2020 22:12:37
User entered 'Yes (Y)'	System	15 Sep 2020 22:12:37

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12' User entered '96.5'	System	15 Sep 2020 22:12:37
	System	15 Sep 2020 22:12:37

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12'	System	15 Sep 2020 22:12:37
User entered 'No (N)'	System	15 Sep 2020 22:12:37



US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12'	System	15 Sep 2020 22:12:37
User entered '15 Sep 2020 17:12'	System	15 Sep 2020 22:12:37

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 19:23'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e' User entered 'Yes (Y)'	System	16 Sep 2020 14:33:42
	System	16 Sep 2020 14:33:42

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e' User entered '96.5'	System	16 Sep 2020 14:33:42
	System	16 Sep 2020 14:33:42

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e' User entered 'No (N)'	System	16 Sep 2020 14:33:42
	System	16 Sep 2020 14:33:42

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e' User entered '16 Sep 2020 09:33'	System	16 Sep 2020 14:33:42
	System	16 Sep 2020 14:33:42



US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 20:18'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 2'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4' User entered 'Yes (Y)'	System	16 Sep 2020 20:30:07
	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4' User entered '97.4'	System	16 Sep 2020 20:30:07
	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4' User entered 'No (N)'	System	16 Sep 2020 20:30:07
	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4' User entered '16 Sep 2020 15:29'	System	16 Sep 2020 20:30:07
	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:42:14



US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 3'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:17:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193' User entered 'Yes (Y)'	System	17 Sep 2020 22:18:14
	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:17:55', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193' User entered '96.3'	System	17 Sep 2020 22:18:14
	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:17:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193'	System	17 Sep 2020 22:18:14
User entered 'No (N)'	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193'	System	17 Sep 2020 22:18:14
User entered '17 Sep 2020 17:18'	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:42:14



US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 4'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38'	System	18 Sep 2020 20:06:32
User entered 'Yes (Y)'	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38' User entered '97.9'	System	18 Sep 2020 20:06:32
	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38'	System	18 Sep 2020 20:06:32
User entered 'No (N)'	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38'	System	18 Sep 2020 20:06:32
User entered '18 Sep 2020 15:06'	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 5'	System	15 Sep 2020 21:42:14



US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5' User entered 'Yes (Y)'	System	19 Sep 2020 19:51:23
	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5' User entered '97.4'	System	19 Sep 2020 19:51:23
	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5'	System	19 Sep 2020 19:51:23
User entered 'No (N)'	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:21', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5' User entered '19 Sep 2020 14:51'	System	19 Sep 2020 19:51:23
	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 6'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:29:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da' User entered 'Yes (Y)'	System	20 Sep 2020 18:30:06
	System	20 Sep 2020 18:30:06



US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:29:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da' User entered '97.3'	System	20 Sep 2020 18:30:06
	System	20 Sep 2020 18:30:06

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:29:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da' User entered 'No (N)'	System	20 Sep 2020 18:30:06
	System	20 Sep 2020 18:30:06

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:03', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da' User entered '20 Sep 2020 13:30'	System	20 Sep 2020 18:30:06
	System	20 Sep 2020 18:30:06

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 7'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7' User entered 'Yes (Y)'	System	21 Sep 2020 18:20:56
	System	21 Sep 2020 18:20:56

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7' User entered '96.4'	System	21 Sep 2020 18:20:56
	System	21 Sep 2020 18:20:56



US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7'	System	21 Sep 2020 18:20:56
User entered 'No (N)'	System	21 Sep 2020 18:20:56

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7'	System	21 Sep 2020 18:20:56
User entered '21 Sep 2020 13:20'	System	21 Sep 2020 18:20:56

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'None (1)'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'No (N)'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'No (N)'	System	15 Sep 2020 22:14:49



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'None (1)'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered '15 Sep 2020 17:14'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 19:23'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437' User entered 'None (1)'	System	16 Sep 2020 14:34:53
	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered 'No (N)'	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered 'No (N)'	System	16 Sep 2020 14:34:53



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered 'None (1)'	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437' User entered '16 Sep 2020 09:34'	System	16 Sep 2020 14:34:53
	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 20:18'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 2'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018'	System	16 Sep 2020 20:31:03
User entered 'None (1)'	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018' User entered 'No (N)'	System	16 Sep 2020 20:31:03
	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018' User entered 'No (N)'	System	16 Sep 2020 20:31:03
	System	16 Sep 2020 20:31:03



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018'	System	16 Sep 2020 20:31:03
User entered 'None (1)'	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018' User entered '16 Sep 2020 15:31'	System	16 Sep 2020 20:31:03
	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 3'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6'	System	17 Sep 2020 22:18:48
User entered 'None (1)'	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6' User entered 'No (N)'	System	17 Sep 2020 22:18:48
	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6' User entered 'No (N)'	System	17 Sep 2020 22:18:48
	System	17 Sep 2020 22:18:48



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6'	System	17 Sep 2020 22:18:48
User entered 'None (1)'	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6' User entered '17 Sep 2020 17:18'	System	17 Sep 2020 22:18:48
	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 4'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926' User entered 'None (1)'	System	18 Sep 2020 20:07:06
	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926' User entered 'No (N)'	System	18 Sep 2020 20:07:06
	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926' User entered 'No (N)'	System	18 Sep 2020 20:07:06
	System	18 Sep 2020 20:07:06



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926' User entered 'None (1)'	System	18 Sep 2020 20:07:06
	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926' User entered '18 Sep 2020 15:07'	System	18 Sep 2020 20:07:06
	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 5'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c' User entered 'None (1)'	System	19 Sep 2020 19:51:49
	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c' User entered 'No (N)'	System	19 Sep 2020 19:51:49
	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c' User entered 'No (N)'	System	19 Sep 2020 19:51:49
	System	19 Sep 2020 19:51:49



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c' User entered 'None (1)'	System	19 Sep 2020 19:51:49
	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c' User entered '19 Sep 2020 14:51'	System	19 Sep 2020 19:51:49
	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 6'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de' User entered 'None (1)'	System	20 Sep 2020 18:30:31
	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de' User entered 'No (N)'	System	20 Sep 2020 18:30:31
	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de' User entered 'No (N)'	System	20 Sep 2020 18:30:31
	System	20 Sep 2020 18:30:31



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de' User entered 'None (1)'	System	20 Sep 2020 18:30:31
	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de' User entered '20 Sep 2020 13:30'	System	20 Sep 2020 18:30:31
	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 7'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3' User entered 'None (1)'	System	21 Sep 2020 18:21:16
	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3' User entered 'No (N)'	System	21 Sep 2020 18:21:16
	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:05', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3' User entered 'No (N)'	System	21 Sep 2020 18:21:16
	System	21 Sep 2020 18:21:16



US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3' User entered 'None (1)'	System	21 Sep 2020 18:21:16
	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3' User entered '21 Sep 2020 13:21'	System	21 Sep 2020 18:21:16
	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:05', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:42', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'No (N)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:45', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered '15 Sep 2020 17:15'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 19:23'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:42:14



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered 'None (0)'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered 'None (0)'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered 'None (0)'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered 'None (0)'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered 'None (0)'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:14', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered 'None (0)'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered 'No (N)'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b' User entered '16 Sep 2020 09:35'	System	16 Sep 2020 14:35:34
	System	16 Sep 2020 14:35:34



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Sep 2020 20:18'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 2'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered 'None (0)'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered 'None (0)'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered 'None (0)'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered 'None (0)'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered 'None (0)'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered 'None (0)'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered 'No (N)'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190' User entered '16 Sep 2020 15:31'	System	16 Sep 2020 20:31:41
	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 3'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'None (0)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:57', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'None (0)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'None (0)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'None (0)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'None (0)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'None (0)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'No (N)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered '17 Sep 2020 17:19'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:42:14



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 4'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'No (N)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered '18 Sep 2020 15:07'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 5'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered 'None (0)'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:57', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered 'None (0)'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered 'None (0)'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:03', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered 'None (0)'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered 'None (0)'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered 'None (0)'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered 'No (N)'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415' User entered '19 Sep 2020 14:52'	System	19 Sep 2020 19:52:23
	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 6'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:31:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'Yes (Y)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:31:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered '20 Sep 2020 13:31'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:42:14



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 7'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered 'None (0)'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:21', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered 'None (0)'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered 'None (0)'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered 'None (0)'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered 'None (0)'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered 'None (0)'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44



US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered 'No (N)'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a' User entered '21 Sep 2020 13:21'	System	21 Sep 2020 18:21:44
	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '22 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16



US3322353

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:37:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:20

US3322353

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'I'	System	22 Sep 2020 16:52:20

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:38:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:38:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '29 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:38:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:38:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
DataPoint Verified.		04 Mar 2021 19:38:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:57

US3322353

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:59:51
User entered 'I'	System	30 Sep 2020 17:36:57



US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:38:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:38:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '6 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:38:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:38:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:38:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:29

US3322353

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'I'	System	06 Oct 2020 19:49:29

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:39:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:18:08

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:39:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:18:08



US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:39:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:18:08

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'VISIT2'	System	13 Oct 2020 20:18:08

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User accepted default value 'Pre-Dose (PREDOSE)'		13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13:09'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '13 Oct 2020 13:09'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20



US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '68'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'bpm'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'breaths/min'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '128'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'mmHg'	System	13 Oct 2020 20:19:20



US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '78'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'mmHg'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User accepted default value 'Post-Dose (POSTDOSE)'		13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '14:40'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '13 Oct 2020 14:40'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20



US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '54'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'bpm'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'breaths/min'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '146'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'mmHg'	System	13 Oct 2020 20:19:20



US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '83'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'mmHg'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:31

US3322353

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:31

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4)	
	Frances Saubon (b) (4)	13 Oct 2020 19:07:49
	(b) (4)	

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 19:07:49



US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13 Oct 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '14:03'	(b) (4) Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '13 Oct 2020 14:03'	System	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:23
User entered 'ONCE'	System	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:52

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:52



US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13:55'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:19:52

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '13 Oct 2020 13:55'	System	13 Oct 2020 20:19:52

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13:50'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '13 Oct 2020 13:50'	System	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		13 Oct 2020 20:20:07



US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered empty.	System	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:40:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:20:14

US3322353

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '1'	System	13 Oct 2020 20:20:14

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911' User entered 'Yes (Y)'	System	13 Oct 2020 19:41:01
	System	13 Oct 2020 19:41:01

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911' User entered '97.8'	System	13 Oct 2020 19:41:01
	System	13 Oct 2020 19:41:01



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911'	System	13 Oct 2020 19:41:01
User entered 'No (N)'	System	13 Oct 2020 19:41:01

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:55', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911' User entered '13 Oct 2020 14:40'	System	13 Oct 2020 19:41:01
	System	13 Oct 2020 19:41:01

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 14:23'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 16:53'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187' User entered 'Yes (Y)'	System	13 Oct 2020 23:47:17
	System	13 Oct 2020 23:47:17

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:47:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187' User entered '97.2'	System	13 Oct 2020 23:47:17
	System	13 Oct 2020 23:47:17

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:47:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187' User entered 'No (N)'	System	13 Oct 2020 23:47:17
	System	13 Oct 2020 23:47:17



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:47:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187' User entered '13 Oct 2020 18:47'	System	13 Oct 2020 23:47:17
	System	13 Oct 2020 23:47:17

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 17:48'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 2'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:01:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c' User entered 'Yes (Y)'	System	14 Oct 2020 18:02:20
	System	14 Oct 2020 18:02:20

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c' User entered '98.3'	System	14 Oct 2020 18:02:20
	System	14 Oct 2020 18:02:20

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c' User entered 'No (N)'	System	14 Oct 2020 18:02:20
	System	14 Oct 2020 18:02:20

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c' User entered '14 Oct 2020 13:02'	System	14 Oct 2020 18:02:20
	System	14 Oct 2020 18:02:20



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 3'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:15:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2'	System	15 Oct 2020 19:16:05
User entered 'Yes (Y)'	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:15:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2' User entered '97.9'	System	15 Oct 2020 19:16:05
	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:15:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2'	System	15 Oct 2020 19:16:05
User entered 'No (N)'	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2'	System	15 Oct 2020 19:16:05
User entered '15 Oct 2020 14:16'	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:07:49



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 4'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:17:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43' User entered 'Yes (Y)'	System	16 Oct 2020 21:18:07
	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:17:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43' User entered '97.1'	System	16 Oct 2020 21:18:07
	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:17:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43'	System	16 Oct 2020 21:18:07
User entered 'No (N)'	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43'	System	16 Oct 2020 21:18:07
User entered '16 Oct 2020 16:18'	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:07:49



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 5'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84' User entered 'Yes (Y)'	System	17 Oct 2020 22:49:43
	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84' User entered '97.6'	System	17 Oct 2020 22:49:43
	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84'	System	17 Oct 2020 22:49:43
User entered 'No (N)'	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84'	System	17 Oct 2020 22:49:43
User entered '17 Oct 2020 17:49'	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 6'	System	13 Oct 2020 19:07:49



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960' User entered 'Yes (Y)'	System	18 Oct 2020 21:36:18
	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960' User entered '97.6'	System	18 Oct 2020 21:36:18
	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960'	System	18 Oct 2020 21:36:18
User entered 'No (N)'	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960' User entered '18 Oct 2020 16:36'	System	18 Oct 2020 21:36:18
	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 7'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c' User entered 'Yes (Y)'	System	19 Oct 2020 18:39:24
	System	19 Oct 2020 18:39:24



US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c' User entered '98.4'	System	19 Oct 2020 18:39:24
	System	19 Oct 2020 18:39:24

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c' User entered 'No (N)'	System	19 Oct 2020 18:39:24
	System	19 Oct 2020 18:39:24

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c' User entered '19 Oct 2020 13:39'	System	19 Oct 2020 18:39:24
	System	19 Oct 2020 18:39:24

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0' User entered 'None (1)'	System	13 Oct 2020 19:41:28
	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0' User entered 'No (N)'	System	13 Oct 2020 19:41:28
	System	13 Oct 2020 19:41:28



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0' User entered 'No (N)'	System	13 Oct 2020 19:41:28
	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0' User entered 'None (1)'	System	13 Oct 2020 19:41:28
	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0' User entered '13 Oct 2020 14:41'	System	13 Oct 2020 19:41:28
	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 14:23'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 16:53'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd'	System	13 Oct 2020 23:46:00
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd' User entered 'No (N)'	System	13 Oct 2020 23:46:00
	System	13 Oct 2020 23:46:00



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd' User entered 'No (N)'	System	13 Oct 2020 23:46:00
	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd'	System	13 Oct 2020 23:46:00
User entered 'None (1)'	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd' User entered '13 Oct 2020 18:45'	System	13 Oct 2020 23:46:00
	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 17:48'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 2'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78'	System	14 Oct 2020 18:03:11
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78' User entered 'No (N)'	System	14 Oct 2020 18:03:11
	System	14 Oct 2020 18:03:11



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78' User entered 'No (N)'	System	14 Oct 2020 18:03:11
	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78' User entered 'None (1)'	System	14 Oct 2020 18:03:11
	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78' User entered '14 Oct 2020 13:02'	System	14 Oct 2020 18:03:11
	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 3'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered 'None (1)'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:14', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered 'No (N)'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered 'No (N)'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered 'None (1)'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered '15 Oct 2020 14:16'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 4'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'None (1)'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'No (N)'	System	16 Oct 2020 21:18:23



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'No (N)'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'None (1)'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered '16 Oct 2020 16:18'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 5'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813'	System	17 Oct 2020 22:49:56
User entered 'None (1)'	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813' User entered 'No (N)'	System	17 Oct 2020 22:49:56
	System	17 Oct 2020 22:49:56



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813' User entered 'No (N)'	System	17 Oct 2020 22:49:56
	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813'	System	17 Oct 2020 22:49:56
User entered 'None (1)'	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813' User entered '17 Oct 2020 17:49'	System	17 Oct 2020 22:49:56
	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 6'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e' User entered 'None (1)'	System	18 Oct 2020 21:36:36
	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e' User entered 'No (N)'	System	18 Oct 2020 21:36:36
	System	18 Oct 2020 21:36:36



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e' User entered 'No (N)'	System	18 Oct 2020 21:36:36
	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e' User entered 'None (1)'	System	18 Oct 2020 21:36:36
	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e' User entered '18 Oct 2020 16:36'	System	18 Oct 2020 21:36:36
	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 7'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9' User entered 'None (1)'	System	19 Oct 2020 18:39:38
	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9' User entered 'No (N)'	System	19 Oct 2020 18:39:38
	System	19 Oct 2020 18:39:38



US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9' User entered 'No (N)'	System	19 Oct 2020 18:39:38
	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9' User entered 'None (1)'	System	19 Oct 2020 18:39:38
	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9' User entered '19 Oct 2020 13:39'	System	19 Oct 2020 18:39:38
	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'No (N)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered '13 Oct 2020 14:41'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 14:23'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 16:53'	System	13 Oct 2020 19:07:49



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:05', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'No (N)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered '13 Oct 2020 18:46'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '13 Oct 2020 17:48'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 2'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered 'None (0)'	System	14 Oct 2020 18:03:13
	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered 'None (0)'	System	14 Oct 2020 18:03:13
	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered 'None (0)'	System	14 Oct 2020 18:03:13
	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered 'None (0)'	System	14 Oct 2020 18:03:13
	System	14 Oct 2020 18:03:13



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered 'None (0)'	System	14 Oct 2020 18:03:13
	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:03:01', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered 'None (0)'	System	14 Oct 2020 18:03:13
	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:03:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6'	System	14 Oct 2020 18:03:13
User entered 'No (N)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:03:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered '14 Oct 2020 13:03'	System	14 Oct 2020 18:03:13
	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 3'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'No (N)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:55', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered '15 Oct 2020 14:16'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:07:49



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 4'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6' User entered 'None (0)'	System	16 Oct 2020 21:18:44
	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6' User entered 'None (0)'	System	16 Oct 2020 21:18:44
	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6' User entered 'None (0)'	System	16 Oct 2020 21:18:44
	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6' User entered 'None (0)'	System	16 Oct 2020 21:18:44
	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6' User entered 'None (0)'	System	16 Oct 2020 21:18:44
	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6' User entered 'None (0)'	System	16 Oct 2020 21:18:44
	System	16 Oct 2020 21:18:44



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'No (N)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:42', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6' User entered '16 Oct 2020 16:18'	System	16 Oct 2020 21:18:44
	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 5'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:57', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered 'None (0)'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered 'None (0)'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:01', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered 'None (0)'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:03', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered 'None (0)'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered 'None (0)'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered 'None (0)'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered 'No (N)'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered '17 Oct 2020 17:50'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 6'	System	13 Oct 2020 19:07:49



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered 'None (0)'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered 'None (0)'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered 'None (0)'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered 'None (0)'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered 'None (0)'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered 'None (0)'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'No (N)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered '18 Oct 2020 16:36'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 7'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0' User entered 'None (0)'	System	19 Oct 2020 18:40:00
	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0' User entered 'None (0)'	System	19 Oct 2020 18:40:00
	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:45', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0' User entered 'None (0)'	System	19 Oct 2020 18:40:00
	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0' User entered 'None (0)'	System	19 Oct 2020 18:40:00
	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0' User entered 'None (0)'	System	19 Oct 2020 18:40:00
	System	19 Oct 2020 18:40:00



US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0' User entered 'None (0)'	System	19 Oct 2020 18:40:00
	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

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)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'No (N)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:56', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0' User entered '19 Oct 2020 13:39'	System	19 Oct 2020 18:40:00
	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:44:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:44:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '20 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:44:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10



US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:44:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10

US3322353

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:44:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:02

US3322353

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '1'	System	20 Oct 2020 17:20:02

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '27 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:26



US3322353

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'I'	System	28 Oct 2020 16:50:26

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '4 Nov 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:33:55

US3322353

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'I'	System	05 Nov 2020 18:33:55

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:05:36



US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:05:36

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:45:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:05:36

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'VISIT3'	System	10 Nov 2020 20:05:36

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '12:05'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '10 Nov 2020 12:05'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06



US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '78'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'bpm'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '15'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'breaths/min'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '112'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'mmHg'	System	10 Nov 2020 20:06:06



US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '72'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'mmHg'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52

US3322353

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:16

US3322353

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:16

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:27

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:27



US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '13:07'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:27

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered '10 Nov 2020 13:07'	System	10 Nov 2020 20:06:27

US3322353

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:46:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:32

US3322353

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'I'	System	10 Nov 2020 20:06:32

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 64'	System	15 Sep 2020 21:42:14

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-16T12:47:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '2b0e99eb-5140-49e8-a3e8-65a8f71e519a' User entered 'No (N)'	System	16 Nov 2020 18:47:22
	System	16 Nov 2020 18:47:22

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-16T12:47:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '2b0e99eb-5140-49e8-a3e8-65a8f71e519a' User entered 'No (N)'	System	16 Nov 2020 18:47:22
	System	16 Nov 2020 18:47:22

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-16T12:47:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '2b0e99eb-5140-49e8-a3e8-65a8f71e519a' User entered '16 Nov 2020 12:47:18'	System	16 Nov 2020 18:47:22
	System	16 Nov 2020 18:47:22



US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 21:42:14

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:27:26
Data entry locked.	System	15 Sep 2020 21:42:14
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 21:42:14

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590'	System	23 Nov 2020 18:44:57
User entered 'No (N)'	System	23 Nov 2020 18:44:57

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590'	System	23 Nov 2020 18:44:57
User entered 'Yes (Y)'	System	23 Nov 2020 18:44:57

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590'	System	23 Nov 2020 18:44:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 18:44:57

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590' User entered '23 Nov 2020 12:44:46'	System	23 Nov 2020 18:44:57
	System	23 Nov 2020 18:44:57

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-26T12:02:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a460c951-5e04-4cb1-8641-b2f3aef83c37'	System	26 Nov 2020 18:02:22
User entered 'No (N)'	System	26 Nov 2020 18:02:22

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-26T12:02:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a460c951-5e04-4cb1-8641-b2f3aef83c37'	System	26 Nov 2020 18:02:22
User entered 'No (N)'	System	26 Nov 2020 18:02:22

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-26T12:02:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a460c951-5e04-4cb1-8641-b2f3aef83c37' User entered '26 Nov 2020 12:02:20'	System	26 Nov 2020 18:02:22
	System	26 Nov 2020 18:02:22

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-03T15:17:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '446e6c7f-428e-4982-a101-39755781ab74' User entered 'No (N)'	System	03 Dec 2020 21:17:26
	System	03 Dec 2020 21:17:26

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-03T15:17:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '446e6c7f-428e-4982-a101-39755781ab74'	System	03 Dec 2020 21:17:26
User entered 'No (N)'	System	03 Dec 2020 21:17:26

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-03T15:17:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '446e6c7f-428e-4982-a101-39755781ab74' User entered '03 Dec 2020 15:17:22'	System	03 Dec 2020 21:17:26
	System	03 Dec 2020 21:17:26

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-10T12:01:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0e0efc42-3083-40ca-8683-96ec0c2cad5d' User entered 'No (N)'	System	10 Dec 2020 18:01:42
	System	10 Dec 2020 18:01:42

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-10T12:01:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0e0efc42-3083-40ca-8683-96ec0c2cad5d' User entered 'No (N)'	System	10 Dec 2020 18:01:42
	System	10 Dec 2020 18:01:42



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-10T12:01:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0e0efc42-3083-40ca-8683-96ec0c2cad5d' User entered '10 Dec 2020 12:01:35'	System	10 Dec 2020 18:01:42
	System	10 Dec 2020 18:01:42

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-17T12:13:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '28736d76-2e43-4e1f-bdbf-4e0cfc57f79d' User entered 'No (N)'	System	17 Dec 2020 18:13:25
	System	17 Dec 2020 18:13:25

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-17T12:13:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '28736d76-2e43-4e1f-bdbf-4e0cfc57f79d' User entered 'No (N)'	System	17 Dec 2020 18:13:25
	System	17 Dec 2020 18:13:25

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-17T12:13:21', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '28736d76-2e43-4e1f-bdbf-4e0cfc57f79d' User entered '17 Dec 2020 12:13:21'	System	17 Dec 2020 18:13:25
	System	17 Dec 2020 18:13:25

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-24T17:15:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '119a98ee-e9df-4d7f-b3de-82a651a95a07'	System	24 Dec 2020 23:16:14
User entered 'No (N)'	System	24 Dec 2020 23:16:14

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-24T17:16:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '119a98ee-e9df-4d7f-b3de-82a651a95a07'	System	24 Dec 2020 23:16:14
User entered 'No (N)'	System	24 Dec 2020 23:16:14

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-24T17:16:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '119a98ee-e9df-4d7f-b3de-82a651a95a07' User entered '24 Dec 2020 17:16:12'	System	24 Dec 2020 23:16:14
	System	24 Dec 2020 23:16:14

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:47:12



US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-31T13:16:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '945b0e20-e045-4700-9981-fae072bbbf65' User entered 'No (N)'	System	31 Dec 2020 19:16:37
	System	31 Dec 2020 19:16:37

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-31T13:16:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '945b0e20-e045-4700-9981-fae072bbbf65' User entered 'No (N)'	System	31 Dec 2020 19:16:37

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-12-31T13:16:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '945b0e20-e045-4700-9981-fae072bbbf65' User entered '31 Dec 2020 13:16:33'	System	31 Dec 2020 19:16:37
	System	31 Dec 2020 19:16:37

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-07T09:17:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '4284881a-8b3d-414e-9a2d-7a66faa822c1' User entered 'No (N)'	System	07 Jan 2021 15:17:44
	System	07 Jan 2021 15:17:44

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-07T09:17:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '4284881a-8b3d-414e-9a2d-7a66faa822c1' User entered 'No (N)'	System	07 Jan 2021 15:17:44



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-07T09:17:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '4284881a-8b3d-414e-9a2d-7a66faa822c1' User entered '07 Jan 2021 09:17:39'	System	07 Jan 2021 15:17:44
	System	07 Jan 2021 15:17:44

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-14T10:13:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3e102ba5-2a81-4093-8357-467265654e0f' User entered 'No (N)'	System	14 Jan 2021 16:14:10
	System	14 Jan 2021 16:14:10

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-14T10:14:01', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3e102ba5-2a81-4093-8357-467265654e0f' User entered 'No (N)'	System	14 Jan 2021 16:14:10

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-14T10:14:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3e102ba5-2a81-4093-8357-467265654e0f' User entered '14 Jan 2021 10:14:04'	System	14 Jan 2021 16:14:10
	System	14 Jan 2021 16:14:10

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-21T14:09:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c9f2af7-c83a-4fca-8405-19cc0cd3a741' User entered 'No (N)'	System	21 Jan 2021 20:09:54
	System	21 Jan 2021 20:09:54

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-21T14:09:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c9f2af7-c83a-4fca-8405-19cc0cd3a741' User entered 'No (N)'	System	21 Jan 2021 20:09:54
	System	21 Jan 2021 20:09:54

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-21T14:09:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c9f2af7-c83a-4fca-8405-19cc0cd3a741' User entered '21 Jan 2021 14:09:50'	System	21 Jan 2021 20:09:54
	System	21 Jan 2021 20:09:54

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:47:12



US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-28T08:30:45', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '96bdc75c-b2a5-4cc3-abe4-703a8fb4151d' User entered 'No (N)'	System	28 Jan 2021 14:30:57
	System	28 Jan 2021 14:30:57

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-28T08:30:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '96bdc75c-b2a5-4cc3-abe4-703a8fb4151d' User entered 'No (N)'	System	28 Jan 2021 14:30:57
	System	28 Jan 2021 14:30:57

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-01-28T08:30:52', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '96bdc75c-b2a5-4cc3-abe4-703a8fb4151d' User entered '28 Jan 2021 08:30:52'	System	28 Jan 2021 14:30:57
	System	28 Jan 2021 14:30:57

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-05T10:40:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a2b3ca84-8ea9-49f0-b9ff-520e41369c14'	System	05 Feb 2021 16:40:18
User entered 'No (N)'	System	05 Feb 2021 16:40:18

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-05T10:40:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a2b3ca84-8ea9-49f0-b9ff-520e41369c14'	System	05 Feb 2021 16:40:18
User entered 'No (N)'	System	05 Feb 2021 16:40:18



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-05T10:40:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a2b3ca84-8ea9-49f0-b9ff-520e41369c14'	System	05 Feb 2021 16:40:18
User entered '05 Feb 2021 10:40:16'	System	05 Feb 2021 16:40:18

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-11T13:53:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '87efc2db-893c-45b0-91f5-677e413b6247'	System	11 Feb 2021 19:53:20
User entered 'No (N)'	System	11 Feb 2021 19:53:20

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-11T13:53:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '87efc2db-893c-45b0-91f5-677e413b6247'	System	11 Feb 2021 19:53:20
User entered 'No (N)'	System	11 Feb 2021 19:53:20

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-11T13:53:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '87efc2db-893c-45b0-91f5-677e413b6247'	System	11 Feb 2021 19:53:20
User entered '11 Feb 2021 13:53:18'	System	11 Feb 2021 19:53:20

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-18T15:53:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ec46ce18-f62e-4ad9-a0ec-767ea3b3c609'	System	18 Feb 2021 21:54:10
User entered 'No (N)'	System	18 Feb 2021 21:54:10

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-18T15:53:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ec46ce18-f62e-4ad9-a0ec-767ea3b3c609' User entered 'No (N)'	System	18 Feb 2021 21:54:10
	System	18 Feb 2021 21:54:10

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-18T15:54:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ec46ce18-f62e-4ad9-a0ec-767ea3b3c609' User entered '18 Feb 2021 15:54:07'	System	18 Feb 2021 21:54:10
	System	18 Feb 2021 21:54:10

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:47:12



US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-25T08:45:52', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '28ec5030-1c72-497b-a250-0cf11468c4d3' User entered 'No (N)'	System	25 Feb 2021 14:46:02
	System	25 Feb 2021 14:46:02

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-25T08:45:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '28ec5030-1c72-497b-a250-0cf11468c4d3' User entered 'No (N)'	System	25 Feb 2021 14:46:02
	System	25 Feb 2021 14:46:02

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-25T08:45:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '28ec5030-1c72-497b-a250-0cf11468c4d3' User entered '25 Feb 2021 08:45:58'	System	25 Feb 2021 14:46:02
	System	25 Feb 2021 14:46:02

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-05T17:41:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79b62d07-3c46-4bf6-aeb7-f57f17c938dc'	System	05 Mar 2021 23:41:54
User entered 'No (N)'	System	05 Mar 2021 23:41:54

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-05T17:41:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79b62d07-3c46-4bf6-aeb7-f57f17c938dc'	System	05 Mar 2021 23:41:54
User entered 'No (N)'	System	05 Mar 2021 23:41:54



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-05T17:41:52', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79b62d07-3c46-4bf6-aeb7-f57f17c938dc' User entered '05 Mar 2021 17:41:52'	System	05 Mar 2021 23:41:54
	System	05 Mar 2021 23:41:54

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-14T21:26:56', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '36fa8a59-42dd-41bc-bd7c-17ab41a0e338'	System	15 Mar 2021 02:27:10
User entered 'No (N)'	System	15 Mar 2021 02:27:10

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-14T21:27:05', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '36fa8a59-42dd-41bc-bd7c-17ab41a0e338'	System	15 Mar 2021 02:27:10
User entered 'No (N)'	System	15 Mar 2021 02:27:10

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-14T21:27:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '36fa8a59-42dd-41bc-bd7c-17ab41a0e338' User entered '14 Mar 2021 21:27:09'	System	15 Mar 2021 02:27:10
	System	15 Mar 2021 02:27:10

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:47:12



US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-18T19:05:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fe9400ad-cacb-4d10-b2fc-a8227513f636'	System	19 Mar 2021 00:06:30
User entered 'No (N)'	System	19 Mar 2021 00:06:30

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-18T19:05:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fe9400ad-cacb-4d10-b2fc-a8227513f636'	System	19 Mar 2021 00:06:30
User entered 'Yes (Y)'	System	19 Mar 2021 00:06:30

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-18T19:06:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fe9400ad-cacb-4d10-b2fc-a8227513f636'	System	19 Mar 2021 00:06:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 00:06:30

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-18T19:06:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fe9400ad-cacb-4d10-b2fc-a8227513f636' User entered '18 Mar 2021 19:06:17'	System	19 Mar 2021 00:06:30
	System	19 Mar 2021 00:06:30

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-26T14:16:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '6044d563-a191-4898-b660-42bac2acafae' User entered 'No (N)'	System	26 Mar 2021 19:16:49
	System	26 Mar 2021 19:16:49

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-26T14:16:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '6044d563-a191-4898-b660-42bac2acafae' User entered 'No (N)'	System	26 Mar 2021 19:16:49
	System	26 Mar 2021 19:16:49

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-03-26T14:16:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '6044d563-a191-4898-b660-42bac2acafae' User entered '26 Mar 2021 14:16:46'	System	26 Mar 2021 19:16:49
	System	26 Mar 2021 19:16:49

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-01T10:10:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a3c90283-77a6-436a-bb99-5fe2f90156f0' User entered 'No (N)'	System	01 Apr 2021 15:10:26
	System	01 Apr 2021 15:10:26



US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-01T10:10:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a3c90283-77a6-436a-bb99-5fe2f90156f0' User entered 'No (N)'	System	01 Apr 2021 15:10:26
	System	01 Apr 2021 15:10:26

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-01T10:10:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'a3c90283-77a6-436a-bb99-5fe2f90156f0' User entered '01 Apr 2021 10:10:23'	System	01 Apr 2021 15:10:26
	System	01 Apr 2021 15:10:26

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-08T19:50:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0350d6f8-9dbe-48fc-8fcd-8d6c35948d9e'	System	09 Apr 2021 00:51:13
User entered 'No (N)'	System	09 Apr 2021 00:51:13

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-08T19:50:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0350d6f8-9dbe-48fc-8fcd-8d6c35948d9e'	System	09 Apr 2021 00:51:13
User entered 'No (N)'	System	09 Apr 2021 00:51:13

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-08T19:51:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0350d6f8-9dbe-48fc-8fcd-8d6c35948d9e'	System	09 Apr 2021 00:51:13
User entered '08 Apr 2021 19:51:07'	System	09 Apr 2021 00:51:13



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-15T10:22:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ee49dc92-d5e5-4e8f-a279-082f1b1a6e51'	System	15 Apr 2021 15:22:21
User entered 'No (N)'	System	15 Apr 2021 15:22:21

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-15T10:22:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ee49dc92-d5e5-4e8f-a279-082f1b1a6e51'	System	15 Apr 2021 15:22:21
User entered 'No (N)'	System	15 Apr 2021 15:22:21

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-15T10:22:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ee49dc92-d5e5-4e8f-a279-082f1b1a6e51' User entered '15 Apr 2021 10:22:17'	System	15 Apr 2021 15:22:21
	System	15 Apr 2021 15:22:21

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-22T16:44:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5dac5588-373a-40f6-b286-5d8edae47d95'	System	22 Apr 2021 21:45:06
User entered 'No (N)'	System	22 Apr 2021 21:45:06

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-22T16:44:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5dac5588-373a-40f6-b286-5d8edae47d95' User entered 'No (N)'	System	22 Apr 2021 21:45:06

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-22T16:45:03', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5dac5588-373a-40f6-b286-5d8edae47d95' User entered '22 Apr 2021 16:45:03'	System	22 Apr 2021 21:45:06
	System	22 Apr 2021 21:45:06

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-29T11:19:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7fd21511-be91-43ec-935f-4d418052ecd5' User entered 'No (N)'	System	29 Apr 2021 16:21:41
	System	29 Apr 2021 16:21:41



US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-29T11:19:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7fd21511-be91-43ec-935f-4d418052ecd5' User entered 'No (N)'	System	29 Apr 2021 16:21:41

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-04-29T11:19:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7fd21511-be91-43ec-935f-4d418052ecd5'	System	29 Apr 2021 16:21:41
User entered '29 Apr 2021 11:19:27'	System	29 Apr 2021 16:21:41

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:47:12

**US3322353**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:47:12



US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:27

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:47:12



**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:47:12

**US3322353**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:06:27**

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)	25 Apr 2021 19:20:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-28T13:08:55', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dae690dd-cc12-4e08-a3ed-60f2ee8a8a2d'	System	28 Feb 2021 19:09:03
User entered 'No (N)'	System	28 Feb 2021 19:09:03



US3322353

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:20:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2021-02-28T13:09:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dae690dd-cc12-4e08-a3ed-60f2ee8a8a2d' User entered '28 Feb 2021 13:09:00'	System	28 Feb 2021 19:09:03
	System	28 Feb 2021 19:09:03

US3322353

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:50:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:14:27

US3322353

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:50:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:14:27

US3322353

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:50:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:14:27

US3322353

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:50:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:14:27

US3322353

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
DataPoint Verified.		04 Mar 2021 19:51:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:06:01
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:14:29

US3322353

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:37:52
User entered 'I'	System	07 Dec 2020 18:14:29

US3322353

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 18:05:20



US3322353

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '08 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 18:05:20

US3322353

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 18:05:20

US3322353

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 18:05:20

US3322353

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		13 Apr 2021 19:29:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 18:05:11

US3322353

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
User entered 'I'	System	11 Jan 2021 18:05:11

US3322353

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 19:40:29

US3322353

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '08 Feb 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 19:40:29

US3322353

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 19:40:29



US3322353

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 19:40:29

US3322353

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		04 Mar 2021 19:51:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 19:40:33

US3322353

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
User entered 'I'	System	21 Feb 2021 19:40:33

US3322353

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		25 Mar 2021 17:10:31
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:58:33

US3322353

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		25 Mar 2021 17:10:31
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
User entered '09 Mar 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:58:33

US3322353

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		25 Mar 2021 17:10:31
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:58:33

US3322353

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		25 Mar 2021 17:10:31
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:58:33

US3322353

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
DataPoint Verified.		25 Mar 2021 17:10:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:58:38



US3322353

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:38:57
User entered 'I'	System	10 Mar 2021 19:58:38

US3322353

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:30:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	30 Mar 2021 22:03:52

US3322353

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:30:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered '30 Mar 2021'	Elisa Moralez (b) (4)	30 Mar 2021 22:03:52

US3322353

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:30:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	30 Mar 2021 22:03:52

**US3322353**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:27**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 22:03:52

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered 'No (N)'	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57



US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

**US3322353**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 22:03:57



US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:07
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 22:03:57

US3322353

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:00
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered 'No (N)'	Elisa Moralez (b) (4)	30 Mar 2021 22:04:00

US3322353

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:34:00
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered empty.	Elisa Moralez (b) (4)	30 Mar 2021 22:04:00

US3322353

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:33:42
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	30 Mar 2021 22:04:06

US3322353

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:33:42
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered '30 Mar 2021'	Elisa Moralez (b) (4)	30 Mar 2021 22:04:06



US3322353

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:33:42
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered '14:23'	Elisa Moralez (b) (4)	30 Mar 2021 22:04:06

**US3322353**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:23'	System	30 Mar 2021 22:04:06

US3322353

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:30:45
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:50
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	30 Mar 2021 22:04:09

**US3322353**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 22:04:09

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:17:57

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:17:57

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:17:57

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 19:17:57



US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:13

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:07:41

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:13

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
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 09:07:41

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:13

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:13

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:13

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:13



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:56:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:13

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	26 Jan 2021 19:19:13

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered empty.	System	26 Jan 2021 19:19:13

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:57:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:31

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:57:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:31

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:57:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '12:51'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:31

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '26 Jan 2021 12:51'	System	26 Jan 2021 19:19:31

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:57:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:40



US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:57:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:40

US3322353

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
DataPoint Verified.		04 Mar 2021 19:57:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '12:46'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 19:19:40

US3322353

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:06:27**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:59:14
User entered '26 Jan 2021 12:46'	System	26 Jan 2021 19:19:40

US3322353

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:06:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:24:32
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:46:18

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:35:32
Reviewed for Safety.		29 Oct 2020 13:44:26
User entered 'USA-US060-2020-mRNA-1273-P301000007'	System	29 Oct 2020 13:44:21
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 13:44:21

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:58:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Adenocarcinoma of prostate - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 23:41:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 23:41:35
Data point term sent to Coder	System	13 Nov 2020 18:46:47
DataPoint Un-verified.	Frances Saubon (b) (4)	13 Nov 2020 18:46:45
Coding entries removed.	Frances Saubon (b) (4)	13 Nov 2020 18:46:45
User entered 'PROSTATE adenocarcinoma' reason for change: New Information	Frances Saubon (b) (4)	13 Nov 2020 18:46:45
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:27:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:27:45
Data point term sent to Coder	System	28 Oct 2020 15:49:29
User entered 'Prostate Cancer'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02



US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:58:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	Frances Saubon (b) (4)	13 Nov 2020 18:46:45
User entered '16 Oct 2020' reason for change: New Information	Frances Saubon (b) (4)	13 Nov 2020 18:46:45
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '23 Oct 2020'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:59:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	Elisa Moralez (b) (4)	12 Feb 2021 15:50:46
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	12 Feb 2021 15:50:46
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Yes (Y)'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:59:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:36:48
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'ok' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 15:50:52
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 15:50:46
User entered '08 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 15:50:46
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 19:33:42
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:44:27

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'Noted, please note that medical records are pending and data will be updated once available. ' (Site from Safety).	Frances Saubon (b) (4)	09 Dec 2020 21:29:33
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 13:23:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:19:47
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' answered with 'As per the latest information per patient, patient reported a plan for surgery for prostate adenocarcinoma on 08-Dec-2020. ' (Site from Safety).	Frances Saubon (b) (4)	01 Dec 2020 22:29:51
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:41:04
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:55:42

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Noted, thank you' (Site from Safety).	Frances Saubon (b) (4)	09 Nov 2020 14:30:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:02:01
		02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	



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Folder: Adverse Events

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Oct 2020 15:49:43
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Oct 2020 15:49:02
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '1' reason for change: Data Entry Error	Frances Saubon (b) (4)	28 Oct 2020 15:49:43
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02



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Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Please refer to concomitant procedure log for Prostate Biopsy and Prostate MRI' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:42:37
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	Frances Saubon (b) (4) (b) (4)	21 Dec 2020 20:30:10
User entered 'I'	(b) (4), (b) (6)	17 Dec 2020 12:35:26
		02 Nov 2020 22:35:32
	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:59:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Elisa Moralez (b) (4)	24 Feb 2021 21:25:15
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:36:41
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available.' answered with 'ok' (Site from Safety).	Elisa Moralez (b) (4)	12 Feb 2021 15:50:56
DataPoint Un-verified.	Elisa Moralez (b) (4)	12 Feb 2021 15:50:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	12 Feb 2021 15:50:46
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 19:34:04
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:44:36
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available.' answered with 'Noted, please note that medical records are pending and data will be updated once available.' (Site from Safety).	Frances Saubon (b) (4)	09 Dec 2020 21:29:38
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 13:23:57
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:19:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'As per the latest information per patient, patient reported a plan for surgery for prostate adenocarcinoma on 08-Dec-2020. ' (Site from Safety).	Frances Saubon (b) (4)	01 Dec 2020 22:29:59
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:02:17
		02 Nov 2020 22:35:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:59:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	Elisa Moralez (b) (4)	24 Feb 2021 21:25:15
User entered 'Urinary Incontinence and Erectile Dysfunction' reason for change: New Information	Elisa Moralez (b) (4)	24 Feb 2021 21:25:15
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "VACUUM ERECTION DEVICE (VED), CT OF ABDOMEN/PELVIC AND BONE SCAN." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 17:46:33
Query 'Per DM CLR: Narrative indicates that subject had "VACUUM ERECTION DEVICE (VED), CT OF ABDOMEN/PELVIC AND BONE SCAN." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'adding' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:56:42
User opened query 'Per DM CLR: Narrative indicates that subject had "VACUUM ERECTION DEVICE (VED), CT OF ABDOMEN/PELVIC AND BONE SCAN." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 06:09:51
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:39:21
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:05:47



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject called our site on 27 OCT 2020 to let us know that on Friday 23 OCT 2020 he found out that he has prostate cancer. Biopsy of prostate was on 16 OCT 2020 thus start date was changed. Patient presented for Urology follow-up S/P Robotic assisted Prostatectomy, bilateral pelvic lymph node dissection, neuroplasty, bladder suspension on 06JAN2021. Patient had surgery on 08DEC2020 (event end date). Patient's hospital stay uncomplicated and without incident. Patient discharged from hospital in stable condition on 09DEC2020. Patient is recovering well; Has been referred for Pelvic Floor Physical Therapy due to urinary incontinence. Patient also has continuing Erectile Dysfunction and is using a Vacuum Erection Device (VED). CT of Abdomen/Pelvic and Bone scan negative for metastatic disease on NOV 2020. Grading: pT3b N1 (1/7) R0 GG 5 prostate CA. One lymph node noted to be positive, will await repeat PSA to determine next steps, possibly radiation. PSA on 06JAN2021 <0.02 (Reference range <0.10 after radical Prostatectomy). At present, medical condition is stabilized and resolved with sequelae. Next follow up for surveillance scheduled for April 2021. Patient is clinically stable at present and will continue with cancer surveillance per Urologist's recommendations.' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	24 Feb 2021 22:13:28
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:20:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:27

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Per source: MR review reveals: hx of long-term elevated PSA, negative prostate bx 2015, PSA 5.9 7/21/2020, MRI prostate w/wo contrast 9/25/20: bladder distended with a couple of diverticula posteriorly measuring up to 1.2 cm, pronounced colonic diverticulosis, B inguinal herniorrhaphy, probability ECE approximately 24%, PI-RADS 4, BPH with obstruction/lower urinary tract symptoms, Rx cipro 500 mg bid 9/29/20 - 10/2/20 and flagyl 500 mg tid 9/29/20 - 10/2/20, prostate bx 10/16/20 adenocarcinoma Gleason 4 + 5 = 9, Revatio for pulmonary hypertension was discontinued on 11/18/2020 per his urologist. He was offered XRT/chemotherapy vs prostatectomy and decided to proceed with prostatectomy, which is scheduled 12/8/20. Discussed with Dr Fragoso and the subject remains eligible to continue in the study since he had already received his 2nd IP 10/13/20.' (Site from Safety).	Frances Saubon (b) (4)	13 Nov 2020 18:51:35
DataPoint Un-verified.	(b) (4)	
User entered 'Subject called our site on 27 OCT 2020 to let us know that on Friday 23 OCT 2020 he found out that he has prostate cancer. Biopsy of prostate was on 16 OCT 2020 thus start date was changed.' reason for change: New Information	Frances Saubon (b) (4)	13 Nov 2020 18:47:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:41:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Per source, MR review reveals: hx of long-term elevated PSA, negative prostate bx 2015, PSA 5.9 7/21/2020, MRI prostate w/wo contrast 9/25/20: bladder distended with a couple of diverticula posteriorly measuring up to 1.2 cm, pronounced colonic diverticulosis, B inguinal herniorrhaphy, probability ECE approximately 24%, PI-RADS 4, BPH with obstruction/lower urinary tract symptoms Rx cipro 500 mg bid 9/29/20 - 10/2/20 and flagyl 500 mg tid 9/29/20 - 10/2/20, prostate bx 10/16/20 adenocarcinoma Gleason 4 + 5 = 9, Revatio for pulmonary hypertension discontinued 11/18/2020. Left upper extremity with no erythema, warmth, tenderness or edema, no left axillary lymphadenopathy. Discussed with PI and the subject remains eligible to continue in the study.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	10 Nov 2020 22:02:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:02:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		06 Nov 2020 18:02:30
DataPoint Verified.		02 Nov 2020 22:35:32
User entered 'Subject called our site on 27 OCT 2020 to let us know that on Friday 23 OCT 2020 he found out that he has prostate cancer.'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 17:06:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:49:02

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 17:06:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:49:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
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: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:18:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:18:42
Data point term sent to Coder	System	10 Nov 2020 21:17:28
User entered 'Gastroesophageal Reflux Disease'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '03 Nov 2020'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

**US3322353**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

**US3322353**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:17:01



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'I'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:40:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 09 Jun 2021 17:06:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 21:17:01

**US3322353**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Lower urinary tract symptoms, LLT: Lower urinary tract symptoms - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Nov 2020 21:35:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:35:49
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Lower urinary tract symptoms, LLT: Lower urinary tract symptoms - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:19:48
Data point term sent to Coder	System	10 Nov 2020 21:18:29
User entered 'lower urinary tract symptoms'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '29 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
User entered empty.	System	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '02 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
User entered empty.	System	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4)	
	Elisa Moralez (b) (4)	10 Nov 2020 21:17:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46



US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'I'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
DataPoint Verified.		04 Mar 2021 20:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46



US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
User entered '0'	System	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51
User entered '1'	System	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:25:51

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Colonic diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:46:49
Data point term sent to Coder	System	13 Nov 2020 18:45:42
User entered 'colonic diverticulosis'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '25 Sep 2020'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49



US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:38:53
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'the AE is still ongoing.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Nov 2020 18:29:26
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 10:05:35
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49



US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'I'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:44:49

US3322353

**Folder:** Adverse Events

**Form:** Adverse Events (4)

**Generated On:** 09 Jun 2021 17:06:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:44:49

**US3322353**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Bladder disorders NEC, PT: Bladder diverticulum, LLT: Bladder diverticulum - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:52:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:52:33
Data point term sent to Coder	System	13 Nov 2020 18:46:47
User entered 'bladder diverticula'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53



US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '25 Sep 2020'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

**US3322353**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:06:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

**US3322353**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:06:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:45:53



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'I'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:44:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 18:45:53

US3322353

**Folder:** Adverse Events

**Form:** Adverse Events (5)

**Generated On:** 09 Jun 2021 17:06:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:45:53

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 17:06:27**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:16
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:48:22



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:50:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:50:49
Data point term sent to Coder	System	27 Sep 2020 02:49:42
User entered 'Testosterone cypionate'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'erectile dysfunction'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please consider recording dose in "mg" as there are multiple dose option available for this Con Med and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:47:17
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please consider recording dose in "mg" as there are multiple dose option available for this Con Med and update as appropriate. ' answered with 'updated per updated source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:52:45
User entered '750' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:52:34
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please consider recording dose in "mg" as there are multiple dose option available for this Con Med and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:05:50
User entered '0.5'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:52:34
User entered 'mL (mL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'other (OTHER)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'every 10 days'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 1987'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Sep 2020 02:49:35



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Sep 2020 02:49:35

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:51:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:51:49
Data point term sent to Coder	System	27 Sep 2020 02:50:42
User entered 'Finasteride'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'benign prostatic hyperplasia'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '5'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2014'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:50:20

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:50:20

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: ALFUZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:52:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:52:50
Data point term sent to Coder	System	27 Sep 2020 02:51:42
User entered 'Alfuzosin'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'benign prostatic hyperplasia'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '10'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2014'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: OTHER POTASSIUM-SPARING AGENTS, PRODUCT: TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:51:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:51:49
Data point term sent to Coder	System	30 Oct 2020 21:51:05
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:50:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: OTHER POTASSIUM-SPARING AGENTS, PRODUCT: TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:33:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:33:36
Data point term sent to Coder	System	27 Sep 2020 02:52:43
User entered 'triamterene'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:49:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#10) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:32:07
Comment added 'Query has been resolved, please see Frances Saubon updated log.'	(b) (4)	14 Dec 2020 17:05:21
DataPoint Un-verified.	Frances Saubon (b) (4)	14 Dec 2020 17:05:06
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	14 Dec 2020 17:05:06
Comment added 'Correction per previous query reply; please disregard reply for this query. This query is still currently being reviewed. Thank you.'	Frances Saubon (b) (4)	14 Dec 2020 15:57:00
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#10) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'per source patient reported she have taken medication at morning of Day 5 since she had a symptom at Day 4,' (Site from DM).	Frances Saubon (b) (4)	14 Dec 2020 15:52:37
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#10) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:38:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4)	27 Sep 2020 02:51:58



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
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 MH eCRF.'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:47:40
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
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 MH eCRF.'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:52:11
' answered with 'updated, thank you' (Site from DM).		
User entered 'pedal edema' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:50:53
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 MH eCRF.'	(b) (4), (b) (6)	30 Oct 2020 11:06:03
(Site from DM).		
User entered 'edema of the feet'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '25'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN May 2020'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:58

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:51:58



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:28:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:28:02
Data point term sent to Coder	System	09 Dec 2020 19:27:28
Coding entries removed.	Frances Saubon (b) (4)	09 Dec 2020 19:27:10
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:45:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:45:35
Data point term sent to Coder	System	27 Sep 2020 02:52:44
User entered 'multi vitamin'	Frances Saubon (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:49:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	(b) (4)	
	Frances Saubon (b) (4)	09 Dec 2020 19:27:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Frances Saubon (b) (4)	09 Dec 2020 19:27:10
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:52:32
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:49:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	(b) (4)	
	Frances Saubon (b) (4)	09 Dec 2020 19:27:10
User entered 'General Health' reason for change:	(b) (4)	
Data Entry Error	Frances Saubon (b) (4)	09 Dec 2020 19:27:10
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Supplements'	Frances Saubon (b) (4)	27 Sep 2020 02:52:32
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'I'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'tablet (TABLET)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 1975'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:52:32



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:52:32

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:26:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:26:57
Data point term sent to Coder	System	09 Dec 2020 19:26:27
Coding entries removed.	Frances Saubon (b) (4)	09 Dec 2020 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:28:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:28:43
Data point term sent to Coder	System	27 Sep 2020 02:53:44
User entered 'folic acid'	Frances Saubon (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:49:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:34:45
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:26:50
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:25:40
User entered 'Yes (Y)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:25:40
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:39:12
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:49:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	(b) (4)	
	Frances Saubon (b) (4)	09 Dec 2020 19:25:40
User entered 'General Health' reason for change: Per	(b) (4)	
Query Resolution	Frances Saubon (b) (4)	09 Dec 2020 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Supplements'	Frances Saubon (b) (4)	27 Sep 2020 02:53:10
	(b) (4)	

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '400'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:47:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated per updated source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:50:05
User entered 'ug (ug)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:49:55
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:05:39
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 1985'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:10

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:50:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: OTHER ANTIDIARRHEALS, ATC: OTHER ANTIDIARRHEALS, PRODUCT: PLANTAGO PSYLLIUM, PRODUCTSYNONYM: PSYLLIUM [PLANTAGO PSYLLIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 15:57:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 15:57:42
Data point term sent to Coder	System	01 Dec 2020 18:32:59
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	01 Dec 2020 18:32:36
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated per updated source, thank you' (Site from System).	Elisa Moralez (b) (4)	01 Dec 2020 18:32:36
DataPoint Un-verified.	Elisa Moralez (b) (4)	01 Dec 2020 18:32:24
User entered 'Psyllium Fiber Supplement' reason for change: New Information	Elisa Moralez (b) (4)	01 Dec 2020 18:32:24
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 09:09:10
Data point term sent to Coder	System	10 Nov 2020 21:22:34

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Elisa Moralez (b) (4)	10 Nov 2020 21:22:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:26:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:26:53
Data point term sent to Coder	System	27 Sep 2020 02:54:45
User entered 'Metamucil'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:50:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	Elisa Moralez (b) (4)	10 Nov 2020 21:22:05
User entered 'IRRITABLE BOWEL SYNDROME'	Elisa Moralez (b) (4)	10 Nov 2020 21:22:05
reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'irritable bowel syndrome constipation prevention'	Frances Saubon (b) (4)	27 Sep 2020 02:53:52



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:50:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:35:03
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:28:02
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:27:58
User entered '10' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:27:58
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:39:24
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '11000'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:50:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	(b) (4)	
	Frances Saubon (b) (4)	09 Dec 2020 19:27:58
User entered 'g (g)' reason for change: Data Entry Error	(b) (4)	09 Dec 2020 19:27:58
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4)	27 Sep 2020 02:53:52
	(b) (4)	

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2015'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:55:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:55:52
Data point term sent to Coder	System	27 Sep 2020 02:54:45
User entered 'Imodium'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'irritable bowel syndrome'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '1/2'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'tablet (TABLET)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2016'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:09:19
User closed query 'Per source subject stopped medication on 20Sep2020. Please confirm with source and update accordingly.' (Site from CRA).		23 Mar 2021 03:08:59
Query 'Per source subject stopped medication on 20Sep2020. Please confirm with source and update accordingly.' answered with 'updated, thank you' (Site from CRA).	Elisa Moralez (b) (4)	09 Mar 2021 22:17:55
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Elisa Moralez (b) (4)	09 Mar 2021 22:17:47
User entered 'No (N)' reason for change: New Information	(b) (4)	
DataPoint Verified.	Elisa Moralez (b) (4)	09 Mar 2021 22:17:47
	(b) (4)	
User opened query 'Per source subject stopped medication on 20Sep2020. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:01:50
User signature succeeded.		05 Mar 2021 19:01:41
	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
DataPoint Verified.	(b) (4)	
	Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
	(b) (4)	
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'		13 Oct 2020 20:24:00
	Frances Saubon (b) (4)	27 Sep 2020 02:54:31
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:09:08
DataPoint Un-verified.	Elisa Moralez (b) (4)	09 Mar 2021 22:17:47
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 22:17:47
User entered '20 Sep 2020' reason for change: New Information	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 22:17:47
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 19:01:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Un-verified.	(b) (4) Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
User entered empty; reason for change New Information	(b) (4) Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '20 Sep 2020' reason for change: Data Entry Error		13 Oct 2020 20:24:00
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User entered '1'	System	27 Sep 2020 02:54:31

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User entered '1'	System	27 Sep 2020 02:54:31



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:54
User entered '804 (804)'	System	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Please update the concomitant procedures page. Per source, it states that the subject had a prostate biopsy on 16 Oct 2020. Please confirm and update accordingly.' (Site from CRA). Query 'Please update the concomitant procedures page. Per source, it states that the subject had a prostate biopsy on 16 Oct 2020. Please confirm and update accordingly.' answered with 'Concomitant procedures page has been updated accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:46:33
User opened query 'Please update the concomitant procedures page. Per source, it states that the subject had a prostate biopsy on 16 Oct 2020. Please confirm and update accordingly.' (Site from CRA). DataPoint Verified.	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:42:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: DESMOPRESSIN - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	02 Nov 2020 22:38:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
Data point term sent to Coder User entered 'Desmopressin'	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:58:16
	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:58:16
	System	13 Oct 2020 20:25:38
	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Urinary Incontinence'		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0.2'		13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'other (OTHER)'		13 Oct 2020 20:24:50



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (v) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'one tablet 2-3 times a week'		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.		13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '6 Oct 2020'		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'		13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.		13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'		13 Oct 2020 20:24:50



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:24:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:30:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:30:56
Data point term sent to Coder Coding entries removed.	System Frances Saubon (b) (4)	09 Dec 2020 19:29:29 09 Dec 2020 19:28:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:41
Data point term sent to Coder User entered 'omeprazole'	System Elisa Moralez (b) (4)	10 Nov 2020 21:24:44 10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User closed query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis instead of the Con Med. Please reconcile with the MH or AE eCRF as necessary.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:36:20
Query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis instead of the Con Med. Please reconcile with the MH or AE eCRF as necessary.' answered with 'updated, entry error' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:28:52
User entered 'Gastroesophageal reflux disease' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:28:43
User opened query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis instead of the Con Med. Please reconcile with the MH or AE eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:38:14
User entered 'omeprazole'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '40'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mg (mg)'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'twice daily (BID)'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '04 Nov 2020'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:51:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 21:24:29

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:24:29

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 02:32:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:32:46
Data point term sent to Coder	System	10 Nov 2020 21:25:46
User entered 'ciprofloxacin'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'lower urinary tract symptoms'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '500'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'twice daily (BID)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '29 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '02 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
DataPoint Verified.		04 Mar 2021 20:52:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
User entered '2'	System	10 Nov 2020 21:25:06

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
User entered '1'	System	10 Nov 2020 21:25:06

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:00
User entered '804 (804)'	System	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 14:58:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:58:32
Data point term sent to Coder	System	10 Nov 2020 21:26:49
User entered 'metronidazole'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'lower urinary tract symptoms'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '500'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'three times daily (TID)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '29 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '02 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
DataPoint Verified.		04 Mar 2021 20:52:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
User entered '3'	System	10 Nov 2020 21:25:50

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
User entered '1'	System	10 Nov 2020 21:25:50



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:02
User entered '804 (804)'	System	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: OTHER ANTIHYPERTENSIVES, ATC: ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:27:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	10 Nov 2020 21:27:40
Data point term sent to Coder	System	10 Nov 2020 21:26:49
User entered 'Sildenafil'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'pulmonary hypertension'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '20'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mg (mg)'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'three times daily (TID)'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '19 Nov 2019' reason for change: New Information	Frances Saubon (b) (4)	13 Nov 2020 18:56:47
User entered '16 Oct 2020'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:52:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	Elisa Moralez (b) (4)	10 Nov 2020 21:26:26



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 21:26:26

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:26:26

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
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.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 21:28:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:28:42
Data point term sent to Coder	System	10 Nov 2020 21:27:50
User entered 'Sildenafil'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'erectile dysfunction'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '100'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'as needed (PRN)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'un UNK 1998'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '16 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
DataPoint Verified.		04 Mar 2021 20:53:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
User entered empty.	System	10 Nov 2020 21:27:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
User entered empty.	System	10 Nov 2020 21:27:01

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:06
User entered empty.	System	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: GENTAMICIN SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 03:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:51:44
Data point term sent to Coder	System	10 Nov 2020 21:27:50
User entered 'gentamicin sulfate'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'lower urinary tract symptoms'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '80'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'once (ONCE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '29 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '29 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
DataPoint Verified.		04 Mar 2021 20:53:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
User entered empty.	System	10 Nov 2020 21:27:40

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
User entered empty.	System	10 Nov 2020 21:27:40

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:09
User entered empty.	System	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:23:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:23:44
Data point term sent to Coder	System	09 Apr 2021 16:22:19
User entered 'Influenza vaccine'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52



US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered 'Prophylaxis of influenza'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered '0.5'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered 'mL (mL)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered 'Intramuscular (INTRAMUSCULAR)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:06:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered '14 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered '0'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered '14 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:32:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:25:29
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:21:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:06:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User entered empty.	System	09 Apr 2021 16:21:52

US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User entered empty.	System	09 Apr 2021 16:21:52



US3322353

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:06:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:13
User entered empty.	System	09 Apr 2021 16:21:52

US3322353

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 17:06:27**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:32
DataPoint Verified.		04 Mar 2021 20:54:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:25

US3322353

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:06:27**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
Signature has been broken.	(b) (4)	
	Elisa Moralez (b) (4)	09 Mar 2021 22:18:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:45:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
	(b) (4)	
User entered '16 Oct 2020'	Blessing Felix-Okoroji	03 Nov 2020 14:40:57
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:45:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Prostate Biopsy'	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:57

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:45:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Diagnostic (DIAGNOSTIC)'	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:57

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:27

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:45:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:57

US3322353

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 17:06:27**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:22
DataPoint Verified.		04 Mar 2021 20:46:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '25 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:22
DataPoint Verified.		04 Mar 2021 20:46:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Prostate Magnetic Resonance Imaging with or with out contrast'	(b) (4) Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:22
DataPoint Verified.		04 Mar 2021 20:46:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:22
DataPoint Verified.		04 Mar 2021 20:46:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:28
DataPoint Verified.		04 Mar 2021 20:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '08 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:07:51

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:28
DataPoint Verified.		04 Mar 2021 20:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Robotic assisted Prostatectomy, bilateral pelvic lymph node dissection, neuroplasty, bladder suspension'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:07:51

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:28
DataPoint Verified.		04 Mar 2021 20:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'Medical History (MH)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:07:51

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:28
DataPoint Verified.		04 Mar 2021 20:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:07:51

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:06:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:30
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4)	20 Apr 2021 19:20:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:27:15
Comment added 'per physician who reviewed medical records, "Results from CT and Bone Scan are from the physician's note, not the actual copy of studies. So only 11/2020 was given in the physician's narrative. Sorry, received MR did not give specific date. I went through the records again."'.	Elisa Moralez (b) (4)	24 Mar 2021 19:24:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Mar 2021 19:57:31
User entered 'un Nov 2020' (non-conformant).	Elisa Moralez (b) (4)	22 Mar 2021 19:57:31

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:06:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:30
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered 'Computerized Tomography (CT) of Abdomen/Pelvis'	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:57:31



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:30
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:57:31

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:06:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:30
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:57:31

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:06:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:33
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4)	
DataPoint Verified.	KC Joubran (b) (4)	20 Apr 2021 19:21:05
	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:27:15
Comment added 'Please note patient does not know exact dates and medical records received are only note and results, so they do not have the exact date. Please resolve query as information is unavailable.'	Elisa Moralez (b) (4)	13 Apr 2021 13:43:35
	(b) (4)	
Comment added 'per physician who reviewed medical records, "Results from CT and Bone Scan are from the physician's note, not the actual copy of studies. So only 11/2020 was given in the physician's narrative. Sorry, received MR did not give specific date. I went through the records again."'.	Elisa Moralez (b) (4)	24 Mar 2021 19:24:52
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Mar 2021 19:57:42
User entered 'un Nov 2020' (non-conformant).	Elisa Moralez (b) (4)	22 Mar 2021 19:57:42
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:06:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:33
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered 'Bone Scan'	Elisa Moralez (b) (4)	22 Mar 2021 19:57:42

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:33
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:57:42

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:06:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:33
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:57:42

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:06:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:35
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4)	
DataPoint Verified.	KC Joubran (b) (4)	20 Apr 2021 19:21:17
	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:27:15
Comment added 'Please note patient does not know exact dates and medical records received are only note and results, so they do not have the exact date. Please resolve query as information is unavailable.'	Elisa Moralez (b) (4)	13 Apr 2021 13:43:52
	(b) (4)	
Comment added 'per physician who reviewed medical records, "Results from CT and Bone Scan are from the physician's note, not the actual copy of studies. So only 11/2020 was given in the physician's narrative. Sorry, received MR did not give specific date. I went through the records again."'.	Elisa Moralez (b) (4)	24 Mar 2021 19:25:09
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Mar 2021 19:57:53
User entered 'un Nov 2020' (non-conformant).	Elisa Moralez (b) (4)	22 Mar 2021 19:57:53
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:06:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:35
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered 'Vacuum Erection Device'	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:57:53



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:06:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:35
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered 'Medical History (MH)'	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 19:57:53

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:06:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:35
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:35:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:27:15
User entered empty.	Elisa Moralez (b) (4)	22 Mar 2021 19:57:53

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Teresa'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Becker'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

**US3322353**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:27**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered empty.	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
	(b) (4)	
User entered '5'	System	25 Feb 2021 16:49:33
User entered '4'	System	16 Feb 2021 17:40:36
User entered '3'	System	02 Dec 2020 15:18:02
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Teresa'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Becker'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered empty.	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
	(b) (4)	
User entered '5'	System	25 Feb 2021 16:49:33
User entered '4'	System	16 Feb 2021 17:40:36
User entered '3'	System	02 Dec 2020 15:18:02
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:27

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '29/Oct/2020 13:46'	(b) (4) System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'I'		29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Teresa'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Becker'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered empty.	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
	(b) (4)	
User entered '5'	System	25 Feb 2021 16:49:33
User entered '4'	System	16 Feb 2021 17:40:36
User entered '3'	System	02 Dec 2020 15:18:02
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

**US3322353**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:06:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '16/Nov/2020 09:21'	(b) (4) System	16 Nov 2020 14:21:03

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:06:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:17:54
User entered 'I'		16 Nov 2020 14:21:03

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Teresa'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Becker'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered empty.	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
	(b) (4)	
User entered '5'	System	25 Feb 2021 16:49:33
User entered '4'	System	16 Feb 2021 17:40:36
User entered '3'	System	02 Dec 2020 15:18:02
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:06:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '02/Dec/2020 15:18'	(b) (4) System	02 Dec 2020 15:18:02

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:06:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
User entered 'I'		02 Dec 2020 15:18:02



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Teresa'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Becker'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered empty.	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
	(b) (4)	
User entered '5'	System	25 Feb 2021 16:49:33
User entered '4'	System	16 Feb 2021 17:40:36
User entered '3'	System	02 Dec 2020 15:18:02
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20



**US3322353**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:06:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '16/Feb/2021 12:40'	(b) (4) System	16 Feb 2021 17:40:36

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:06:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
User entered '1'		16 Feb 2021 17:40:36

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Teresa'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered 'Becker'	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:41:01
Un-reviewed for Safety.	System	16 Feb 2021 17:40:36
User entered empty.	System	16 Feb 2021 17:40:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21



US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
	(b) (4)	
User entered '5'	System	25 Feb 2021 16:49:33
User entered '4'	System	16 Feb 2021 17:40:36
User entered '3'	System	02 Dec 2020 15:18:02
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:06:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered '25/Feb/2021 16:49'	(b) (4) System	25 Feb 2021 16:49:33

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:06:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:05:47
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 16:49:33