

US3362285 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:16:03

All time stamps listed in this document are displayed in GMT

US3362285

Form: Participant Creation

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

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Participant ID

US3362285

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

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US3362285

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3362285

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:39:25

Generated On: 09 Jun 2021 17:16:03

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3362285

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:39:25

Generated On: 09 Jun 2021 17:16:03

Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 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

US3362285

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:39:25

Generated On: 09 Jun 2021 17:16:03

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3362285

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

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Were any significant conditions reported?

Yes ☒  
No ☐

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US3362285

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3362285

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	HYPERLIPIDEMIA
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)	_____

US3362285

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3362285

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	BENIGN PROSTATE HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3362285

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	LUMBAR DISCETOMY
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

US3362285

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	RIGHT VASCULAR STENT PLACEMENT
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

US3362285

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	DRUG ALLERGY - PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1955
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 1955
Start Year (derived)	1955
Stop Month and Year (derived)	
Stop Year (derived)	

US3362285

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	DRUG ALLERGY - CLARITHROMYCIN
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)	

US3362285

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	DRUG ALLERGY - STATINS
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	



US3362285

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	GENERALIZED ARTHRITIS
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)	

US3362285

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3362285

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Condition	ERECTILE DISEASE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3362285

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:22 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:22
Height ( <i>xxx.x</i> )	183 cm
Weight ( <i>xxx.x</i> )	118.6 kg
BMI ( <i>xxx.x</i> )	35.41461 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)	

US3362285

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

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.*

US3362285

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

US3362285

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:39:27

Generated On: 09 Jun 2021 17:16:03

<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)	True
<b>Other</b>	False
<b>Specify</b>	

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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



US3362285

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

What was the date of randomization? (dd MMM yyyy) 24 SEP 2020

What was the participant's randomization number? 189374

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 ☒

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Height	ND - Not Done
Weight	ND - Not Done

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

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)	24 SEP 2020
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:36
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

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)	24 SEP 2020
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:22
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3362285

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

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.*

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 09:46 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 09:46

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

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	09:02 (24 HR)
Collection date and time (derived)	24 SEP 2020 09:02

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:08	24 SEP 2020 09:08
Nasopharyngeal Swab 2	No		



US3362285

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 10:21

PC Open Date & Time

24 SEP 2020 10:06

PC Close Date & Time

24 SEP 2020 12:36

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**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 98.0 °F

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

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

PC Time Stamp	24 SEP 2020 20:26
PC Open Date & Time	24 SEP 2020 13:31
PC Close Date & Time	25 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**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

98.2 °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

25 SEP 2020 12:42

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**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

97.5 °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

26 SEP 2020 14:07

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 13:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**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

97.1 °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

28 SEP 2020 21:21

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

29 SEP 2020 12:54

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**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

96.1 °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

30 SEP 2020 14:24

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**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

24 SEP 2020 10:22

PC Open Date & Time

24 SEP 2020 10:06

PC Close Date & Time

24 SEP 2020 12:36

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**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

24 SEP 2020 20:27

PC Open Date & Time

24 SEP 2020 13:31

PC Close Date & Time

25 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**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

25 SEP 2020 12:43

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**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

26 SEP 2020 14:08

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**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

27 SEP 2020 13:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**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

28 SEP 2020 21:21

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**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

29 SEP 2020 12:55

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**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

30 SEP 2020 14:24

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**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 ☐

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 10:24
PC Open Date & Time	24 SEP 2020 10:06
PC Close Date & Time	24 SEP 2020 12:36

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**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 ☐

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 20:28
PC Open Date & Time	24 SEP 2020 13:31
PC Close Date & Time	25 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2137

EAB) (1725)

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:43
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

55 of 2137



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 14:09
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

57 of 2137

EAB) (1725)

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 13:36
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

59 of 2137

EAB) (1725)

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 21:22
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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 ☒

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:55
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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 ☒



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 14:25
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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



US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

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)	22 OCT 2020
Time of assessment (00:00-23:59)	08:00 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 08:00
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 10:22
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3362285

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

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) 22 OCT 2020

What was the treatment time? (00:00-23:59) 08:42 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 08:42

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

What was the frequency of the study treatment dosing? ONCE

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

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

08:11 (24 HR)

Collection date and time (derived)

22 OCT 2020 08:11

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:10	22 OCT 2020 08:10
Nasopharyngeal Swab 2	No		

US3362285

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**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

22 OCT 2020 09:16

PC Open Date & Time

22 OCT 2020 09:02

PC Close Date & Time

22 OCT 2020 11:32



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**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 97.3 °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	22 OCT 2020 13:58
PC Open Date & Time	22 OCT 2020 12:27
PC Close Date & Time	23 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 12:30

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 12:16

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 13:39

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**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

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

26 OCT 2020 14:45

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 12:55

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

28 OCT 2020 17:46

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 OCT 2020 09:02

PC Close Date & Time

22 OCT 2020 11:32



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**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

22 OCT 2020 13:59

PC Open Date & Time

22 OCT 2020 12:27

PC Close Date & Time

23 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**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

23 OCT 2020 12:31

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**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

24 OCT 2020 12:17

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**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

25 OCT 2020 13:40

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**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

26 OCT 2020 14:45

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**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

27 OCT 2020 12:57

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**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

28 OCT 2020 17:47

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**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 ☐



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

22 OCT 2020 09:02

PC Close Date & Time

22 OCT 2020 11:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**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 ☐

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 14:00
PC Open Date & Time	22 OCT 2020 12:27
PC Close Date & Time	23 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2137

EAB) (1725)

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 12:33
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 12:18
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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 ☒



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 13:40
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

105 of 2137

EAB) (1725)

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 14:46
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 12:59
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 17:48
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3362285

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	07:42 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 07:42
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362285

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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



US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 NOV 2020

Collection time (00:00-23:59)

07:55 (24 HR)

Collection date and time (derived)

16 NOV 2020 07:55

US3362285

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 01:45:56

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 61
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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2020 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 NOV 2020 08:19:45
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 12:08:32
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 00:33:25
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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

19 DEC 2020 12:30:10

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59



US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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	27 DEC 2020 11:54:27
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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

06 JAN 2021 03:44:01

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	13 JAN 2021 08:14:21
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 09:29:28

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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	26 JAN 2021 06:18:26
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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	01 FEB 2021 12:01:13
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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

08 FEB 2021 12:25:09

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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	15 FEB 2021 13:33:59
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59



US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 07:24:09
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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

27 FEB 2021 00:13:34

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 07:00:22
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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

13 MAR 2021 16:41:33

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 01:56:31
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 13:53:24

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 02:55:32
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 10:04:18
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59



US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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

17 APR 2021 08:53:36

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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

24 APR 2021 13:03:32

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 MAY 2021 03:34:24
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59
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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 369

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 474

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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°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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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°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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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°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 ☐



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	03 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 SEP 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59
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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59
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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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="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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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 <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"/>



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**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 ☐

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

12 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

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US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

26 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

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30 NOV 2022 23:59

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US3362285

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 17:16:03**

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		06 MAR 2021 07:01:04



US3362285

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:28:49

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:28:49

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362285

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3362285

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Visit date (dd MMM yyyy)	
--------------------------	--

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

Folder OID	
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US3362285

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

US3362285

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

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.*

US3362285

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3362285**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:16:03**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362285

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:03

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"/>

**US3362285**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:16:03**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3362285

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

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

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

Visit date (dd MMM yyyy)	15 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3362285

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

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Date of updated informed consent (dd MMM yyyy) 15 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) 15 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 \_\_\_\_\_

US3362285

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

08:53 (24 HR)

Collection date and time (derived)

15 JAN 2021 08:53

US3362285

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00 - 23:59)

08:56

Collection Date and Time (derived)

15 JAN 2021 08:56

US3362285

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:21:44

Generated On: 09 Jun 2021 17:16:03

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:44:12

Generated On: 09 Jun 2021 17:16:03

AEID	USA-US112-2020-MRNA-1273-P30 1000011
Adverse event	CEREBROVASCULAR ACCIDENT
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 NOV 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)	18 NOV 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 type="radio"/> Grade 4 <input checked="" 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	18 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	332 of 2137

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:44:12

Generated On: 09 Jun 2021 17:16:03

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	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:44:12

Generated On: 09 Jun 2021 17:16:03

---

PATIENT CONTACTED SITE  
-SENT TO ER ON NIGHT OF  
16NOV2020 FOR DIFFICULTY  
SPEAKING AND DIAGNOSED  
WITH CEREBROVASCULAR  
ACCIDENT. ADMITTED TO  
HOSPITAL 16NOV-18NOV2020;  
STATED ONLY NEW  
MEDICATION WAS FULL DOSE  
ASPRIN 325MG RIGHT NOW;  
WILL COME TO SIGN MEDICAL  
RELEASE AND UPDATE  
ACCORDINGLY, HAS FOLLOW  
UP WITH CARDIOLOGIST  
REPORTS CAUSE OF CVA LEFT  
CORONARY ARTERY  
OCCLUSION - WILL CONFIRM  
WITH MEDICAL RECORDS.

---

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

---

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:44:12

Generated On: 09 Jun 2021 17:16:03

AEID

Adverse event

SYNCPAL EPISODE

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)

5 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 JAN 2021

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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

335 of 2137

EAB) (1725)



US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:44:12

Generated On: 09 Jun 2021 17:16:03

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 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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 00:44:12

Generated On: 09 Jun 2021 17:16:03

AEID

Adverse event

HEART BLOCK

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)

5 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 FEB 2021

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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

337 of 2137

EAB) (1725)

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 00:44:12

Generated On: 09 Jun 2021 17:16:03

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	False
Concomitant Procedure	True
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)	_____

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Data signed:** (b) (4) 09 Apr 2021 01:00:34

**Generated On: 09 Jun 2021 17:16:03**

---

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

Yes ☒

No ☐

---

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

---

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication LOSARTAN/HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100/25

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

340 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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 2001
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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication ZETIA

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

342 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

344 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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	2001
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication TRULICITY

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 1.5

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

346 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

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

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication JARDIANCE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

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 ☐

PRODUCTION RELEASE (v12.003

348 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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 SEP 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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATE  
HYPERTROPHY

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

350 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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 2013
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"/>



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication FINASTERIDE

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATE  
HYPERTROPHY

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

352 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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 2013
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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication MOBIC

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED ARTHRITIS

Dose per administration 15

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

354 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

356 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16	NOV 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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

358 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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)		11 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)		11 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"/>



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PNEUMONIA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

360 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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)		11 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)		11 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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
CEREBROVASCULAR  
ACCIDENT

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

362 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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)		24 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication CEREBROVASCULAR  
ACCIDENT

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication CEREBROVASCULAR  
ACCIDENT

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

366 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication GLIMEPIRIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

368 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication REPATHA

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 140

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 OTHER WEEK

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

PRODUCTION RELEASE (v12.003

370 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication PRE-OP SURGERY FOR PACE  
MAKER PLACEMENT

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 FEB 2021		
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"/>

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2137

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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 2010	
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"/>



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Name of Medication LEVITRA

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

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

376 of 2137

EAB) (1725)

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

	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 2001	
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"/>

US3362285

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3362285

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 01:00:34

Generated On: 09 Jun 2021 17:16:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 FEB 2021	PACEMAKER	Medical History	

US3362285

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:16:03

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

US3362285

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:03

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 ☐

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

SAEID	USA-US112-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 01:40:31

Generated On: 09 Jun 2021 17:16:03

SAEID	USA-US112-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	24/NOV/2020 00:23
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

US3362285 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362285

Form: Participant Creation

Generated On: 09 Jun 2021 17:16:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'US3362285'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 13:19:26

US3362285

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential (if applicable) and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:20:29
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential (if applicable) and Risk of Exposure eCRF forms. Please update as needed. ' answered with 'data updated per query resolution' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:27:17
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential (if applicable) and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:19:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:00:48

US3362285

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '24 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 13:19:27

US3362285

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 15:00:48

US3362285

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'SCRN'	System	24 Sep 2020 15:00:48

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User closed query 'Per CDM: Demographics data is required, please update the eCRF form as needed. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Demographics data is required, please update the eCRF form as needed. ' answered with 'Data updated per query resolution. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:20:08
User opened query 'Per CDM: Demographics data is required, please update the eCRF form as needed. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:35:18
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 21:19:27
		24 Sep 2020 13:19:29

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '66'	(b) (4), (b) (6)	30 Sep 2020 14:33:45



US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered 'YEARS'	System	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered '66'	System	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered 'Male (M)'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:33:45



US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:33:45

**US3362285**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:16:03**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

**US3362285**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:16:03**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:33:45

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:02:02

**US3362285**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:16:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered 'Sep 2020'	System	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered '2020'	System	24 Sep 2020 15:02:02



US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 15:02:17
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:02:17
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 15:02:02
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 13:19:27

US3362285

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered 'I'	System	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:00:53



US3362285

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:16:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:07:03

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:09:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:09:47
Data point term sent to Coder	System	30 Sep 2020 15:08:29
User entered 'HYPERTENSION'	(b) (4), (b) (6)	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2001'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2001'	System	30 Sep 2020 15:07:34



US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2001'	System	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:07:34

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:09:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:09:47
Data point term sent to Coder	System	30 Sep 2020 15:08:30
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:07:48



US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2018'	System	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2018'	System	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:07:48

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:09:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:09:48
Data point term sent to Coder	System	30 Sep 2020 15:08:30
User entered 'DIABETES TYPE II'	(b) (4), (b) (6)	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2001'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:08:06



US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2001'	System	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2001'	System	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:08:06

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
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 hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:17:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:17:53
Data point term sent to Coder	System	30 Sep 2020 15:08:31
User entered 'BENIGN PROSTASTE HYPERTROPHY'	(b) (4), (b) (6)	30 Sep 2020 15:08:28



US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2013'	System	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2013'	System	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:08:28



US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:08:28

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 17:01:20
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:05:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:10:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:10:50
Data point term sent to Coder	System	30 Sep 2020 15:09:31
User entered 'LUMBAR DISCETOMY'	(b) (4), (b) (6)	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2018'	System	30 Sep 2020 15:08:47



US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2018'	System	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2018'	System	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2018'	System	30 Sep 2020 15:08:47

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Vascular stent insertion, LLT: Vascular stent insertion - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 12:07:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 12:07:33
Data point term sent to Coder	System	30 Sep 2020 15:09:34
User entered 'RIGHT VASCULAR STENT PLACEMENT'	(b) (4), (b) (6)	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:09:09



US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2019'	System	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2019'	System	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2019'	System	30 Sep 2020 15:09:09

**US3362285**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:16:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2019'	System	30 Sep 2020 15:09:09

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:10:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:10:50
Data point term sent to Coder	System	30 Sep 2020 15:09:34
User entered 'DRUG ALLERGY - PENICILLIN'	(b) (4), (b) (6)	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 1955'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:09:29



US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 1955'	System	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '1955'	System	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:09:29

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:19:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:19:55
Data point term sent to Coder	System	30 Sep 2020 15:10:37
User entered 'DRUG ALLERGY - CLARITHROMYCIN'	(b) (4), (b) (6)	30 Sep 2020 15:10:00



US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2015'	System	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2015'	System	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:10:00



US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:10:00

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:13:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:13:54
Data point term sent to Coder	System	30 Sep 2020 15:12:42
User entered 'DRUG ALLERGY - STATINS'	(b) (4), (b) (6)	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2014'	System	30 Sep 2020 15:11:44



US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2014'	System	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	30 Sep 2020 15:11:44

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Generalized arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 15:57:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 15:57:54
Data point term sent to Coder	System	11 Feb 2021 15:56:42
User entered 'GENERALIZED ARTHRITIS'	(b) (4), (b) (6)	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'UN UNK 2018'	(b) (4), (b) (6)	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:56:37



US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2018'	System	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2018'	System	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	11 Feb 2021 15:56:37

US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
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)	07 Apr 2021 16:34:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 16:34:47
Data point term sent to Coder	System	07 Apr 2021 16:33:34
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	07 Apr 2021 16:33:26

US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Apr 2021 16:33:26

US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 16:33:26



US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 16:33:26

US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:33:26

US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 16:33:26

US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2010'	System	07 Apr 2021 16:33:26

**US3362285**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:16:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2010'	System	07 Apr 2021 16:33:26

US3362285

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	07 Apr 2021 16:33:26

**US3362285**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:16:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	07 Apr 2021 16:33:26

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 16:35:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 16:35:33
Data point term sent to Coder	System	07 Apr 2021 16:34:35
User entered 'Erectile disease'	(b) (4), (b) (6)	07 Apr 2021 16:34:01



US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'Jan 2001'	System	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '2001'	System	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	07 Apr 2021 16:34:01



US3362285

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered empty.	System	07 Apr 2021 16:34:01

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '10:22'	(b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '24 Sep 2020 10:22'	System	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '183' cm	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:13:35
DataPoint set to visible.	System	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User closed query 'Per CDM: Please confirm weight and update if necessary. Thank you.' (Site from DM).	(b) (4)	08 Oct 2020 20:24:36
Query 'Per CDM: Please confirm weight and update if necessary. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:34:45
User entered '118.6' kg reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:34:31
User opened query 'Per CDM: Please confirm weight and update if necessary. Thank you.' (Site from DM).		07 Oct 2020 15:02:21
User entered '35.4' kg		30 Sep 2020 15:13:35
DataPoint set to visible.	System	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered '35.41461'	System	07 Oct 2020 18:34:31
User entered '10.57064'	System	30 Sep 2020 15:13:35
DataPoint set to visible.	System	24 Sep 2020 15:02:02



US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'kg/m2'	System	30 Sep 2020 15:13:35
DataPoint set to visible.	System	24 Sep 2020 15:02:02

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Sep 2020 15:13:35

**US3362285**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:16:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'bpm'	System	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'breaths/min'	System	30 Sep 2020 15:13:35



US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'mmHg'	System	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User entered 'mmHg'	System	30 Sep 2020 15:13:35

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57

US3362285

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:13:56

US3362285

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:13:56



US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

[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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

[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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:14:43



US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

**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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:14:43



US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

[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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

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 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:28:57
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:39:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:14:43

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:01:04

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:01:04

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:01:04



US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'VISIT1'	System	24 Sep 2020 15:01:04

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '24 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:36

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '189374'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:36

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:36

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:01:40

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:01:40

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:01:40

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:01:40



US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:01:40

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:14:58
DataPoint set to visible.	System	24 Sep 2020 15:02:17

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 19:48:27
User entered '183' cm reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:05:33
User entered empty.		24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 19:48:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:48:27
User entered '118.6' kg reason for change: Data Entry Error		24 Sep 2020 17:05:33
User entered empty.		24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 19:48:27
User entered '183' cm reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:05:33
User entered empty.		24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 19:48:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:48:27
User entered '118.6' kg reason for change: Data Entry Error		24 Sep 2020 17:05:33
User entered empty.		24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39



US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '08:36'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '24 Sep 2020 08:36'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '72'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'bpm'	System	24 Sep 2020 16:42:39



US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'breaths/min'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '144'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '73'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:48:27
User entered '183' cm reason for change: Data Entry Error		24 Sep 2020 17:05:33
User entered empty.		24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 19:48:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:48:27
User entered '118.6' kg reason for change: Data Entry Error		24 Sep 2020 17:05:33
User entered empty.		24 Sep 2020 16:42:39



US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '10:22'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '24 Sep 2020 10:22'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39



US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '67'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'bpm'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'breaths/min'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '112'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '70'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:42:39

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	24 Sep 2020 16:42:39



US3362285

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	02 Oct 2020 19:49:32
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	02 Oct 2020 19:49:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:42:44

US3362285

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:49:32
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:42:44

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '09:46'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:02:57



US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '24 Sep 2020 09:46'	System	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'ONCE'	System	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 15:02:57

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:15:47

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:15:47

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '09:02'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:15:47

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '24 Sep 2020 09:02'	System	30 Sep 2020 15:15:47



US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '09:08'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '24 Sep 2020 09:08'	System	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:16:06



US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered empty.	System	30 Sep 2020 15:16:06

US3362285

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:16:11

US3362285

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	30 Sep 2020 15:16:11

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:20:16', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5'	System	24 Sep 2020 15:21:41
User entered 'Yes (Y)'	System	24 Sep 2020 15:21:41

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:20:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5'	System	24 Sep 2020 15:21:41
User entered '98.1'	System	24 Sep 2020 15:21:41

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:21:29', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5'	System	24 Sep 2020 15:21:41
User entered 'No (N)'	System	24 Sep 2020 15:21:41

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:21:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5'	System	24 Sep 2020 15:21:41
User entered '24 Sep 2020 10:21'	System	24 Sep 2020 15:21:41



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 10:06'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 12:36'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae'	System	25 Sep 2020 01:26:56
User entered 'Yes (Y)'	System	25 Sep 2020 01:26:56

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae'	System	25 Sep 2020 01:26:56
User entered '98.0'	System	25 Sep 2020 01:26:56

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae'	System	25 Sep 2020 01:26:56
User entered 'No (N)'	System	25 Sep 2020 01:26:56

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:54', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae'	System	25 Sep 2020 01:26:56
User entered '24 Sep 2020 20:26'	System	25 Sep 2020 01:26:56

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 13:31'	System	24 Sep 2020 15:02:57



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 2'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:02', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6'	System	25 Sep 2020 17:42:31
User entered 'Yes (Y)'	System	25 Sep 2020 17:42:31

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:11', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6'	System	25 Sep 2020 17:42:31
User entered '98.2'	System	25 Sep 2020 17:42:31

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6'	System	25 Sep 2020 17:42:31
User entered 'No (N)'	System	25 Sep 2020 17:42:31

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6'	System	25 Sep 2020 17:42:31
User entered '25 Sep 2020 12:42'	System	25 Sep 2020 17:42:31

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:02:57



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 3'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2'	System	26 Sep 2020 19:07:45
User entered 'Yes (Y)'	System	26 Sep 2020 19:07:45

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2'	System	26 Sep 2020 19:07:45
User entered '97.5'	System	26 Sep 2020 19:07:45

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2'	System	26 Sep 2020 19:07:45
User entered 'No (N)'	System	26 Sep 2020 19:07:45

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2'	System	26 Sep 2020 19:07:45
User entered '26 Sep 2020 14:07'	System	26 Sep 2020 19:07:45

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 4'	System	24 Sep 2020 15:02:57



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:34:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09'	System	27 Sep 2020 18:35:14
User entered 'Yes (Y)'	System	27 Sep 2020 18:35:14

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09'	System	27 Sep 2020 18:35:14
User entered '97.5'	System	27 Sep 2020 18:35:14

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09'	System	27 Sep 2020 18:35:14
User entered 'No (N)'	System	27 Sep 2020 18:35:14

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09'	System	27 Sep 2020 18:35:14
User entered '27 Sep 2020 13:35'	System	27 Sep 2020 18:35:14

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 5'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:20:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3'	System	29 Sep 2020 02:21:14
User entered 'Yes (Y)'	System	29 Sep 2020 02:21:14



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:20:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3'	System	29 Sep 2020 02:21:14
User entered '97.1'	System	29 Sep 2020 02:21:14

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3'	System	29 Sep 2020 02:21:14
User entered 'No (N)'	System	29 Sep 2020 02:21:14

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3'	System	29 Sep 2020 02:21:14
User entered '28 Sep 2020 21:21'	System	29 Sep 2020 02:21:14

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 6'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7'	System	29 Sep 2020 17:54:49
User entered 'Yes (Y)'	System	29 Sep 2020 17:54:49

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7' User entered '98.1'	System	29 Sep 2020 17:54:49
	System	29 Sep 2020 17:54:49



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:40', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7'	System	29 Sep 2020 17:54:49
User entered 'No (N)'	System	29 Sep 2020 17:54:49

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:45', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7'	System	29 Sep 2020 17:54:49
User entered '29 Sep 2020 12:54'	System	29 Sep 2020 17:54:49

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 7'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:05', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a'	System	30 Sep 2020 19:24:28
User entered 'Yes (Y)'	System	30 Sep 2020 19:24:28

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a'	System	30 Sep 2020 19:24:28
User entered '96.1'	System	30 Sep 2020 19:24:28

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a'	System	30 Sep 2020 19:24:28
User entered 'No (N)'	System	30 Sep 2020 19:24:28



US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a'	System	30 Sep 2020 19:24:28
User entered '30 Sep 2020 14:24'	System	30 Sep 2020 19:24:28

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:21:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68'	System	24 Sep 2020 15:22:28
User entered 'None (1)'	System	24 Sep 2020 15:22:28

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68'	System	24 Sep 2020 15:22:28
User entered 'No (N)'	System	24 Sep 2020 15:22:28

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68'	System	24 Sep 2020 15:22:28
User entered 'No (N)'	System	24 Sep 2020 15:22:28

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68'	System	24 Sep 2020 15:22:28
User entered 'None (1)'	System	24 Sep 2020 15:22:28



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68'	System	24 Sep 2020 15:22:28
User entered '24 Sep 2020 10:22'	System	24 Sep 2020 15:22:28

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 10:06'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 12:36'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077'	System	25 Sep 2020 01:27:37
User entered 'None (1)'	System	25 Sep 2020 01:27:37

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077'	System	25 Sep 2020 01:27:37
User entered 'No (N)'	System	25 Sep 2020 01:27:37

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077'	System	25 Sep 2020 01:27:37
User entered 'No (N)'	System	25 Sep 2020 01:27:37

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077'	System	25 Sep 2020 01:27:37
User entered 'None (1)'	System	25 Sep 2020 01:27:37



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077'	System	25 Sep 2020 01:27:37
User entered '24 Sep 2020 20:27'	System	25 Sep 2020 01:27:37

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 13:31'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 2'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c'	System	25 Sep 2020 17:43:03
User entered 'None (1)'	System	25 Sep 2020 17:43:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c'	System	25 Sep 2020 17:43:03
User entered 'No (N)'	System	25 Sep 2020 17:43:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:45', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c'	System	25 Sep 2020 17:43:03
User entered 'No (N)'	System	25 Sep 2020 17:43:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c'	System	25 Sep 2020 17:43:03
User entered 'None (1)'	System	25 Sep 2020 17:43:03



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c'	System	25 Sep 2020 17:43:03
User entered '25 Sep 2020 12:43'	System	25 Sep 2020 17:43:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 3'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a'	System	26 Sep 2020 19:08:14
User entered 'None (1)'	System	26 Sep 2020 19:08:14

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:52', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a'	System	26 Sep 2020 19:08:14
User entered 'No (N)'	System	26 Sep 2020 19:08:14

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a'	System	26 Sep 2020 19:08:14
User entered 'No (N)'	System	26 Sep 2020 19:08:14

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:03', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a'	System	26 Sep 2020 19:08:14
User entered 'None (1)'	System	26 Sep 2020 19:08:14



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a'	System	26 Sep 2020 19:08:14
User entered '26 Sep 2020 14:08'	System	26 Sep 2020 19:08:14

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 4'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6'	System	27 Sep 2020 18:35:54
User entered 'None (1)'	System	27 Sep 2020 18:35:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6'	System	27 Sep 2020 18:35:54
User entered 'No (N)'	System	27 Sep 2020 18:35:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6'	System	27 Sep 2020 18:35:54
User entered 'No (N)'	System	27 Sep 2020 18:35:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6'	System	27 Sep 2020 18:35:54
User entered 'None (1)'	System	27 Sep 2020 18:35:54



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6'	System	27 Sep 2020 18:35:54
User entered '27 Sep 2020 13:35'	System	27 Sep 2020 18:35:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 5'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586'	System	29 Sep 2020 02:22:03
User entered 'None (1)'	System	29 Sep 2020 02:22:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586'	System	29 Sep 2020 02:22:03
User entered 'No (N)'	System	29 Sep 2020 02:22:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:28', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586'	System	29 Sep 2020 02:22:03
User entered 'No (N)'	System	29 Sep 2020 02:22:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586'	System	29 Sep 2020 02:22:03
User entered 'None (1)'	System	29 Sep 2020 02:22:03



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586'	System	29 Sep 2020 02:22:03
User entered '28 Sep 2020 21:21'	System	29 Sep 2020 02:22:03

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 6'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4'	System	29 Sep 2020 17:55:18
User entered 'None (1)'	System	29 Sep 2020 17:55:18

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4'	System	29 Sep 2020 17:55:18
User entered 'No (N)'	System	29 Sep 2020 17:55:18

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:59', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4'	System	29 Sep 2020 17:55:18
User entered 'No (N)'	System	29 Sep 2020 17:55:18

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4'	System	29 Sep 2020 17:55:18
User entered 'None (1)'	System	29 Sep 2020 17:55:18



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4'	System	29 Sep 2020 17:55:18
User entered '29 Sep 2020 12:55'	System	29 Sep 2020 17:55:18

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 7'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038'	System	30 Sep 2020 19:24:54
User entered 'None (1)'	System	30 Sep 2020 19:24:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038'	System	30 Sep 2020 19:24:54
User entered 'No (N)'	System	30 Sep 2020 19:24:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038'	System	30 Sep 2020 19:24:54
User entered 'No (N)'	System	30 Sep 2020 19:24:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038'	System	30 Sep 2020 19:24:54
User entered 'None (1)'	System	30 Sep 2020 19:24:54



US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038'	System	30 Sep 2020 19:24:54
User entered '30 Sep 2020 14:24'	System	30 Sep 2020 19:24:54

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered 'None (0)'	System	24 Sep 2020 15:24:45

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered 'None (0)'	System	24 Sep 2020 15:24:45

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered 'None (0)'	System	24 Sep 2020 15:24:45

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered 'None (0)'	System	24 Sep 2020 15:24:45



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:23:02', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered 'None (0)'	System	24 Sep 2020 15:24:45

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:23:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered 'None (0)'	System	24 Sep 2020 15:24:45

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:24:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered 'No (N)'	System	24 Sep 2020 15:24:45

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:24:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674'	System	24 Sep 2020 15:24:45
User entered '24 Sep 2020 10:24'	System	24 Sep 2020 15:24:45

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 10:06'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 12:36'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered 'None (0)'	System	25 Sep 2020 01:28:37



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered 'None (0)'	System	25 Sep 2020 01:28:37

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered 'None (0)'	System	25 Sep 2020 01:28:37

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered 'None (0)'	System	25 Sep 2020 01:28:37

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered 'None (0)'	System	25 Sep 2020 01:28:37

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:15', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered 'None (0)'	System	25 Sep 2020 01:28:37

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered 'No (N)'	System	25 Sep 2020 01:28:37

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604'	System	25 Sep 2020 01:28:37
User entered '24 Sep 2020 20:28'	System	25 Sep 2020 01:28:37

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Sep 2020 13:31'	System	24 Sep 2020 15:02:57



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 2'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered 'None (0)'	System	25 Sep 2020 17:43:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered 'None (0)'	System	25 Sep 2020 17:43:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:16', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered 'None (0)'	System	25 Sep 2020 17:43:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered 'None (0)'	System	25 Sep 2020 17:43:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered 'None (0)'	System	25 Sep 2020 17:43:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered 'None (0)'	System	25 Sep 2020 17:43:58



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered 'No (N)'	System	25 Sep 2020 17:43:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8'	System	25 Sep 2020 17:43:58
User entered '25 Sep 2020 12:43'	System	25 Sep 2020 17:43:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 3'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered 'None (0)'	System	26 Sep 2020 19:09:30

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered 'None (0)'	System	26 Sep 2020 19:09:30

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:38', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered 'None (0)'	System	26 Sep 2020 19:09:30



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered 'None (0)'	System	26 Sep 2020 19:09:30

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:09:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered 'None (0)'	System	26 Sep 2020 19:09:30

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:09:11', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered 'None (0)'	System	26 Sep 2020 19:09:30

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:09:21', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered 'No (N)'	System	26 Sep 2020 19:09:30

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:09:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424'	System	26 Sep 2020 19:09:30
User entered '26 Sep 2020 14:09'	System	26 Sep 2020 19:09:30

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 4'	System	24 Sep 2020 15:02:57



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered 'None (0)'	System	27 Sep 2020 18:36:29

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered 'None (0)'	System	27 Sep 2020 18:36:29

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:02', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered 'None (0)'	System	27 Sep 2020 18:36:29

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered 'None (0)'	System	27 Sep 2020 18:36:29

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered 'None (0)'	System	27 Sep 2020 18:36:29

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered 'None (0)'	System	27 Sep 2020 18:36:29

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered 'No (N)'	System	27 Sep 2020 18:36:29

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f'	System	27 Sep 2020 18:36:29
User entered '27 Sep 2020 13:36'	System	27 Sep 2020 18:36:29



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 5'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered 'None (0)'	System	29 Sep 2020 02:22:52

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered 'None (0)'	System	29 Sep 2020 02:22:52

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered 'None (0)'	System	29 Sep 2020 02:22:52

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:22', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered 'None (0)'	System	29 Sep 2020 02:22:52

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered 'None (0)'	System	29 Sep 2020 02:22:52



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered 'None (0)'	System	29 Sep 2020 02:22:52

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:40', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered 'No (N)'	System	29 Sep 2020 02:22:52

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:47', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a'	System	29 Sep 2020 02:22:52
User entered '28 Sep 2020 21:22'	System	29 Sep 2020 02:22:52

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 6'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:21', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' User entered 'None (0)'	System	29 Sep 2020 17:55:58
	System	29 Sep 2020 17:55:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9'	System	29 Sep 2020 17:55:58
User entered 'None (0)'	System	29 Sep 2020 17:55:58



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' User entered 'None (0)'	System	29 Sep 2020 17:55:58
	System	29 Sep 2020 17:55:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' User entered 'None (0)'	System	29 Sep 2020 17:55:58
	System	29 Sep 2020 17:55:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' User entered 'None (0)'	System	29 Sep 2020 17:55:58
	System	29 Sep 2020 17:55:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:47', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' User entered 'None (0)'	System	29 Sep 2020 17:55:58
	System	29 Sep 2020 17:55:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:52', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9'	System	29 Sep 2020 17:55:58
User entered 'No (N)'	System	29 Sep 2020 17:55:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9'	System	29 Sep 2020 17:55:58
User entered '29 Sep 2020 12:55'	System	29 Sep 2020 17:55:58

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:02:57



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	24 Sep 2020 15:02:57
User entered 'Day 7'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828'	System	30 Sep 2020 19:25:35
User entered 'None (0)'	System	30 Sep 2020 19:25:35

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828'	System	30 Sep 2020 19:25:35
User entered 'None (0)'	System	30 Sep 2020 19:25:35

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:05', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' User entered 'None (0)'	System	30 Sep 2020 19:25:35
	System	30 Sep 2020 19:25:35

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828'	System	30 Sep 2020 19:25:35
User entered 'None (0)'	System	30 Sep 2020 19:25:35

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828'	System	30 Sep 2020 19:25:35
User entered 'None (0)'	System	30 Sep 2020 19:25:35

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:21', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828'	System	30 Sep 2020 19:25:35
User entered 'None (0)'	System	30 Sep 2020 19:25:35

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828'	System	30 Sep 2020 19:25:35
User entered 'No (N)'	System	30 Sep 2020 19:25:35



US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828'	System	30 Sep 2020 19:25:35
User entered '30 Sep 2020 14:25'	System	30 Sep 2020 19:25:35

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:02:57

US3362285

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:02:57

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 15:51:38

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '01 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 15:51:38

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:51:38

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 15:51:38

US3362285

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 15:51:42



US3362285

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	08 Oct 2020 15:51:42

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 15:55:45

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '08 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 15:55:45

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:55:45

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 15:55:45

US3362285

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 15:55:50

**US3362285**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:16:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	08 Oct 2020 15:55:50

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:57:46



US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:57:46

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:57:46

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:57:46

US3362285

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:57:51

US3362285

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	15 Oct 2020 13:57:51

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:17:16

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:17:16

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:17:16



US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'VISIT2'	System	22 Oct 2020 16:17:16

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '08:00'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '22 Oct 2020 08:00'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36



US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '82'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'bpm'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'breaths/min'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '136'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '88'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36



US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User closed query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:12:28
Query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' answered with 'post dose time updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:54:01
User entered '10:22' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:53:50
User opened query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:28:51
User entered '09:00'	(b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '22 Oct 2020 10:22'	System	30 Oct 2020 18:53:50
User entered '22 Oct 2020 09:00'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36



US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '79'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'bpm'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '18'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'breaths/min'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '140'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '76'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:36



US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	22 Oct 2020 16:19:36

US3362285

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:20:55

US3362285

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:20:55

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:11:25



US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '08:42'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '22 Oct 2020 08:42'	System	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'ONCE'	System	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 14:11:25

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:21:20

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:21:20

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '08:11'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:21:20



US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '22 Oct 2020 08:11'	System	22 Oct 2020 16:21:20

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '08:10'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '22 Oct 2020 08:10'	System	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:22:04



US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered empty.	System	22 Oct 2020 16:22:04

US3362285

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:22:10

US3362285

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	22 Oct 2020 16:22:10

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:15:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102'	System	22 Oct 2020 14:16:14
User entered 'Yes (Y)'	System	22 Oct 2020 14:16:14

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:15:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102'	System	22 Oct 2020 14:16:14
User entered '97.8'	System	22 Oct 2020 14:16:14

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:15:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102'	System	22 Oct 2020 14:16:14
User entered 'No (N)'	System	22 Oct 2020 14:16:14



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:16:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102'	System	22 Oct 2020 14:16:14
User entered '22 Oct 2020 09:16'	System	22 Oct 2020 14:16:14

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 09:02'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 11:32'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd'	System	22 Oct 2020 18:58:38
User entered 'Yes (Y)'	System	22 Oct 2020 18:58:38

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:15', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd' User entered '97.3'	System	22 Oct 2020 18:58:38
	System	22 Oct 2020 18:58:38

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd'	System	22 Oct 2020 18:58:38
User entered 'No (N)'	System	22 Oct 2020 18:58:38

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd'	System	22 Oct 2020 18:58:38
User entered '22 Oct 2020 13:58'	System	22 Oct 2020 18:58:38



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 12:27'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 2'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1'	System	23 Oct 2020 17:30:44
User entered 'Yes (Y)'	System	23 Oct 2020 17:30:44

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1'	System	23 Oct 2020 17:30:44
User entered '98.0'	System	23 Oct 2020 17:30:44

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1'	System	23 Oct 2020 17:30:44
User entered 'No (N)'	System	23 Oct 2020 17:30:44

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1'	System	23 Oct 2020 17:30:44
User entered '23 Oct 2020 12:30'	System	23 Oct 2020 17:30:44

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 14:11:25



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 3'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:28', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a'	System	24 Oct 2020 17:17:01
User entered 'Yes (Y)'	System	24 Oct 2020 17:17:01

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a'	System	24 Oct 2020 17:17:01
User entered '97.7'	System	24 Oct 2020 17:17:01

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a'	System	24 Oct 2020 17:17:01
User entered 'No (N)'	System	24 Oct 2020 17:17:01

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a'	System	24 Oct 2020 17:17:01
User entered '24 Oct 2020 12:16'	System	24 Oct 2020 17:17:01

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 14:11:25



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 4'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d'	System	25 Oct 2020 18:39:30
User entered 'Yes (Y)'	System	25 Oct 2020 18:39:30

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d' User entered '96.0'	System	25 Oct 2020 18:39:30
	System	25 Oct 2020 18:39:30

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d'	System	25 Oct 2020 18:39:30
User entered 'No (N)'	System	25 Oct 2020 18:39:30

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d'	System	25 Oct 2020 18:39:30
User entered '25 Oct 2020 13:39'	System	25 Oct 2020 18:39:30

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 5'	System	22 Oct 2020 14:11:25



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:44:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21'	System	26 Oct 2020 19:45:17
User entered 'Yes (Y)'	System	26 Oct 2020 19:45:17

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21' User entered '96.3'	System	26 Oct 2020 19:45:17
	System	26 Oct 2020 19:45:17

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21'	System	26 Oct 2020 19:45:17
User entered 'No (N)'	System	26 Oct 2020 19:45:17

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21'	System	26 Oct 2020 19:45:17
User entered '26 Oct 2020 14:45'	System	26 Oct 2020 19:45:17

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 6'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a'	System	27 Oct 2020 17:55:44
User entered 'Yes (Y)'	System	27 Oct 2020 17:55:44



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a' User entered '97.2'	System	27 Oct 2020 17:55:44
	System	27 Oct 2020 17:55:44

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a'	System	27 Oct 2020 17:55:44
User entered 'No (N)'	System	27 Oct 2020 17:55:44

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a'	System	27 Oct 2020 17:55:44
User entered '27 Oct 2020 12:55'	System	27 Oct 2020 17:55:44

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 7'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d'	System	29 Oct 2020 19:11:58
User entered 'Yes (Y)'	System	29 Oct 2020 19:11:58

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d'	System	29 Oct 2020 19:11:58
User entered '97.3'	System	29 Oct 2020 19:11:58



US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d'	System	29 Oct 2020 19:11:58
User entered 'No (N)'	System	29 Oct 2020 19:11:58

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d'	System	29 Oct 2020 19:11:58
User entered '28 Oct 2020 17:46'	System	29 Oct 2020 19:11:58

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 09:02'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 11:32'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08'	System	22 Oct 2020 18:59:23
User entered 'None (1)'	System	22 Oct 2020 18:59:23



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08'	System	22 Oct 2020 18:59:23
User entered 'No (N)'	System	22 Oct 2020 18:59:23

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08'	System	22 Oct 2020 18:59:23
User entered 'No (N)'	System	22 Oct 2020 18:59:23

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08'	System	22 Oct 2020 18:59:23
User entered 'None (1)'	System	22 Oct 2020 18:59:23

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08'	System	22 Oct 2020 18:59:23
User entered '22 Oct 2020 13:59'	System	22 Oct 2020 18:59:23

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 12:27'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 2'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1'	System	23 Oct 2020 17:31:36
User entered 'None (1)'	System	23 Oct 2020 17:31:36



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1'	System	23 Oct 2020 17:31:36
User entered 'No (N)'	System	23 Oct 2020 17:31:36

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:16', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1'	System	23 Oct 2020 17:31:36
User entered 'No (N)'	System	23 Oct 2020 17:31:36

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1'	System	23 Oct 2020 17:31:36
User entered 'None (1)'	System	23 Oct 2020 17:31:36

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1'	System	23 Oct 2020 17:31:36
User entered '23 Oct 2020 12:31'	System	23 Oct 2020 17:31:36

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 3'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf'	System	24 Oct 2020 17:17:39
User entered 'None (1)'	System	24 Oct 2020 17:17:39



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:11', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf'	System	24 Oct 2020 17:17:39
User entered 'No (N)'	System	24 Oct 2020 17:17:39

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf'	System	24 Oct 2020 17:17:39
User entered 'No (N)'	System	24 Oct 2020 17:17:39

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf'	System	24 Oct 2020 17:17:39
User entered 'None (1)'	System	24 Oct 2020 17:17:39

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf'	System	24 Oct 2020 17:17:39
User entered '24 Oct 2020 12:17'	System	24 Oct 2020 17:17:39

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 4'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438'	System	25 Oct 2020 18:40:04
User entered 'None (1)'	System	25 Oct 2020 18:40:04



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438'	System	25 Oct 2020 18:40:04
User entered 'No (N)'	System	25 Oct 2020 18:40:04

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438'	System	25 Oct 2020 18:40:04
User entered 'No (N)'	System	25 Oct 2020 18:40:04

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438'	System	25 Oct 2020 18:40:04
User entered 'None (1)'	System	25 Oct 2020 18:40:04

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438'	System	25 Oct 2020 18:40:04
User entered '25 Oct 2020 13:40'	System	25 Oct 2020 18:40:04

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 5'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e'	System	26 Oct 2020 19:45:41
User entered 'None (1)'	System	26 Oct 2020 19:45:41



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e'	System	26 Oct 2020 19:45:41
User entered 'No (N)'	System	26 Oct 2020 19:45:41

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:28', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e'	System	26 Oct 2020 19:45:41
User entered 'No (N)'	System	26 Oct 2020 19:45:41

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e'	System	26 Oct 2020 19:45:41
User entered 'None (1)'	System	26 Oct 2020 19:45:41

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e'	System	26 Oct 2020 19:45:41
User entered '26 Oct 2020 14:45'	System	26 Oct 2020 19:45:41

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 6'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524'	System	27 Oct 2020 17:57:26
User entered 'None (1)'	System	27 Oct 2020 17:57:26



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:56:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524'	System	27 Oct 2020 17:57:26
User entered 'No (N)'	System	27 Oct 2020 17:57:26

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:56:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524'	System	27 Oct 2020 17:57:26
User entered 'No (N)'	System	27 Oct 2020 17:57:26

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524'	System	27 Oct 2020 17:57:26
User entered 'None (1)'	System	27 Oct 2020 17:57:26

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524'	System	27 Oct 2020 17:57:26
User entered '27 Oct 2020 12:57'	System	27 Oct 2020 17:57:26

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 7'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc'	System	29 Oct 2020 19:12:00
User entered 'None (1)'	System	29 Oct 2020 19:12:00



US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc'	System	29 Oct 2020 19:12:00
User entered 'No (N)'	System	29 Oct 2020 19:12:00

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc'	System	29 Oct 2020 19:12:00
User entered 'No (N)'	System	29 Oct 2020 19:12:00

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc'	System	29 Oct 2020 19:12:00
User entered 'None (1)'	System	29 Oct 2020 19:12:00

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc'	System	29 Oct 2020 19:12:00
User entered '28 Oct 2020 17:47'	System	29 Oct 2020 19:12:00

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 09:02'	System	22 Oct 2020 14:11:25



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 11:32'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered 'None (0)'	System	22 Oct 2020 19:00:11

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered 'None (0)'	System	22 Oct 2020 19:00:11

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered 'None (0)'	System	22 Oct 2020 19:00:11

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered 'None (0)'	System	22 Oct 2020 19:00:11

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered 'None (0)'	System	22 Oct 2020 19:00:11

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered 'None (0)'	System	22 Oct 2020 19:00:11



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T14:00:03', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered 'No (N)'	System	22 Oct 2020 19:00:11

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T14:00:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6'	System	22 Oct 2020 19:00:11
User entered '22 Oct 2020 14:00'	System	22 Oct 2020 19:00:11

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '22 Oct 2020 12:27'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 2'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered 'None (0)'	System	23 Oct 2020 17:33:04

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered 'No interference with activity (1)'	System	23 Oct 2020 17:33:04

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:29', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered 'None (0)'	System	23 Oct 2020 17:33:04



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered 'None (0)'	System	23 Oct 2020 17:33:04

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered 'None (0)'	System	23 Oct 2020 17:33:04

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered 'None (0)'	System	23 Oct 2020 17:33:04

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered 'No (N)'	System	23 Oct 2020 17:33:04

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:33:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d'	System	23 Oct 2020 17:33:04
User entered '23 Oct 2020 12:33'	System	23 Oct 2020 17:33:04

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 3'	System	22 Oct 2020 14:11:25



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:44', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered 'None (0)'	System	24 Oct 2020 17:18:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:47', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered 'None (0)'	System	24 Oct 2020 17:18:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered 'None (0)'	System	24 Oct 2020 17:18:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered 'None (0)'	System	24 Oct 2020 17:18:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:18:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered 'None (0)'	System	24 Oct 2020 17:18:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:18:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered 'None (0)'	System	24 Oct 2020 17:18:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:18:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered 'No (N)'	System	24 Oct 2020 17:18:32

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:18:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665'	System	24 Oct 2020 17:18:32
User entered '24 Oct 2020 12:18'	System	24 Oct 2020 17:18:32



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 4'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:15', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered 'None (0)'	System	25 Oct 2020 18:40:55

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered 'None (0)'	System	25 Oct 2020 18:40:55

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered 'None (0)'	System	25 Oct 2020 18:40:55

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered 'None (0)'	System	25 Oct 2020 18:40:55

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered 'None (0)'	System	25 Oct 2020 18:40:55



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered 'None (0)'	System	25 Oct 2020 18:40:55

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered 'No (N)'	System	25 Oct 2020 18:40:55

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e'	System	25 Oct 2020 18:40:55
User entered '25 Oct 2020 13:40'	System	25 Oct 2020 18:40:55

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 5'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered 'None (0)'	System	26 Oct 2020 19:46:15

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:45', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered 'None (0)'	System	26 Oct 2020 19:46:15



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered 'None (0)'	System	26 Oct 2020 19:46:15

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:52', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered 'None (0)'	System	26 Oct 2020 19:46:15

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered 'None (0)'	System	26 Oct 2020 19:46:15

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:59', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered 'None (0)'	System	26 Oct 2020 19:46:15

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:46:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered 'No (N)'	System	26 Oct 2020 19:46:15

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:46:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad'	System	26 Oct 2020 19:46:15
User entered '26 Oct 2020 14:46'	System	26 Oct 2020 19:46:15

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 14:11:25



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 6'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered 'None (0)'	System	27 Oct 2020 17:59:38

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered 'None (0)'	System	27 Oct 2020 17:59:38

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered 'None (0)'	System	27 Oct 2020 17:59:38

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered 'None (0)'	System	27 Oct 2020 17:59:38

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered 'None (0)'	System	27 Oct 2020 17:59:38

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:44', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered 'None (0)'	System	27 Oct 2020 17:59:38

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:59:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered 'No (N)'	System	27 Oct 2020 17:59:38



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:59:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6'	System	27 Oct 2020 17:59:38
User entered '27 Oct 2020 12:59'	System	27 Oct 2020 17:59:38

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
Data entry locked.	System	22 Oct 2020 14:11:25
User entered 'Day 7'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered 'None (0)'	System	29 Oct 2020 19:11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered 'None (0)'	System	29 Oct 2020 19:11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered 'None (0)'	System	29 Oct 2020 19:11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered 'None (0)'	System	29 Oct 2020 19:11:59



US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered 'None (0)'	System	29 Oct 2020 19:11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered 'None (0)'	System	29 Oct 2020 19:11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:48:03', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered 'No (N)'	System	29 Oct 2020 19:11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:48:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50'	System	29 Oct 2020 19:11:59
User entered '28 Oct 2020 17:48'	System	29 Oct 2020 19:11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 14:11:25

US3362285

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:16:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:03:13
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 14:11:25

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 22:00:42

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 22:00:42



US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:00:42

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:00:42

US3362285

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:47:42

US3362285

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	05 Nov 2020 17:47:42

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:41

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:41

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:41

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:41



US3362285

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:46

**US3362285**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:16:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	05 Nov 2020 17:52:46

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 19:47:56

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 19:47:56

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:47:56

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:47:56

US3362285

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 19:47:45

US3362285

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	12 Nov 2020 19:47:45



US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:25:06

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:25:06

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:25:06

**US3362285**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:16:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'VISIT3'	System	16 Nov 2020 15:25:06

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '07:42'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '16 Nov 2020 07:42'	System	16 Nov 2020 15:55:00



US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '89'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'bpm'	System	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '18'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'breaths/min'	System	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '139'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00



US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '72'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'mmHg'	System	16 Nov 2020 15:55:00

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58

US3362285

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:40

US3362285

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:55:40

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:57:05



US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:57:05

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered '07:55'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:57:05

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered '16 Nov 2020 07:55'	System	16 Nov 2020 15:57:05

US3362285

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	22 Feb 2021 01:45:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:57:13

US3362285

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	16 Nov 2020 15:57:13

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:34:03

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:33:33
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'no AEs reported ' (Site from DM).	Amy Thomassie (b) (4)	06 Mar 2021 22:07:24
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:48:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-11-29T08:17:52', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ad0a4459-64a9-4525-99ff-db9e90a49257'	System	29 Nov 2020 14:19:55
User entered 'Yes (Y)'	System	29 Nov 2020 14:19:55

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2020-11-29T08:18:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ad0a4459-64a9-4525-99ff-db9e90a49257'	System	29 Nov 2020 14:19:55
User entered 'No (N)'	System	29 Nov 2020 14:19:55

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-11-29T08:18:29', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ad0a4459-64a9-4525-99ff-db9e90a49257'	System	29 Nov 2020 14:19:55
User entered 'No (N)'	System	29 Nov 2020 14:19:55

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-11-29T08:18:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ad0a4459-64a9-4525-99ff-db9e90a49257'	System	29 Nov 2020 14:19:55
User entered 'Yes (Y)'	System	29 Nov 2020 14:19:55

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Please 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 (1db0398f97ba671b)', Time: '2020-11-29T08:19:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ad0a4459-64a9-4525-99ff-db9e90a49257'	System	29 Nov 2020 14:19:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 14:19:55

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-11-29T08:19:45', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ad0a4459-64a9-4525-99ff-db9e90a49257'	System	29 Nov 2020 14:19:55
User entered '29 Nov 2020 08:19:45'	System	29 Nov 2020 14:19:55

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:34:03

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2020-12-07T12:08:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3ae54009-a9d2-4d2d-993c-360552da66e6'	System	07 Dec 2020 18:08:37
User entered 'No (N)'	System	07 Dec 2020 18:08:37

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2020-12-07T12:08:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3ae54009-a9d2-4d2d-993c-360552da66e6'	System	07 Dec 2020 18:08:37
User entered 'No (N)'	System	07 Dec 2020 18:08:37

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-12-07T12:08:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3ae54009-a9d2-4d2d-993c-360552da66e6' User entered '07 Dec 2020 12:08:32'	System	07 Dec 2020 18:08:37
	System	07 Dec 2020 18:08:37

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2020-12-12T00:32:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3488ebd0-0de1-426d-a9e1-a60e9fe45797'	System	12 Dec 2020 06:33:27
User entered 'No (N)'	System	12 Dec 2020 06:33:27

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2020-12-12T00:32:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3488ebd0-0de1-426d-a9e1-a60e9fe45797'	System	12 Dec 2020 06:33:27
User entered 'No (N)'	System	12 Dec 2020 06:33:27

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-12-12T00:33:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3488ebd0-0de1-426d-a9e1-a60e9fe45797'	System	12 Dec 2020 06:33:27
User entered '12 Dec 2020 00:33:25'	System	12 Dec 2020 06:33:27

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:34:03

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2020-12-19T12:29:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '732ccfd4-301a-4342-a4d3-c9625b952110'	System	19 Dec 2020 18:30:13
User entered 'No (N)'	System	19 Dec 2020 18:30:13

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2020-12-19T12:30:05', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '732ccfd4-301a-4342-a4d3-c9625b952110'	System	19 Dec 2020 18:30:13
User entered 'No (N)'	System	19 Dec 2020 18:30:13



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-12-19T12:30:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '732ccfd4-301a-4342-a4d3-c9625b952110'	System	19 Dec 2020 18:30:13
User entered '19 Dec 2020 12:30:10'	System	19 Dec 2020 18:30:13

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:34:03

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2020-12-27T11:54:03', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0349c64a-11b2-40a9-8614-0d59cff66777'	System	27 Dec 2020 17:54:28
User entered 'No (N)'	System	27 Dec 2020 17:54:28

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2020-12-27T11:54:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0349c64a-11b2-40a9-8614-0d59cff66777'	System	27 Dec 2020 17:54:28
User entered 'No (N)'	System	27 Dec 2020 17:54:28

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-12-27T11:54:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0349c64a-11b2-40a9-8614-0d59cff66777'	System	27 Dec 2020 17:54:28
User entered '27 Dec 2020 11:54:27'	System	27 Dec 2020 17:54:28

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-01-06T03:43:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f271dd34-4458-4332-8bb6-fb7964d42070'	System	06 Jan 2021 09:44:03
User entered 'No (N)'	System	06 Jan 2021 09:44:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-01-06T03:43:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f271dd34-4458-4332-8bb6-fb7964d42070'	System	06 Jan 2021 09:44:03
User entered 'No (N)'	System	06 Jan 2021 09:44:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-01-06T03:44:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f271dd34-4458-4332-8bb6-fb7964d42070'	System	06 Jan 2021 09:44:03
User entered '06 Jan 2021 03:44:01'	System	06 Jan 2021 09:44:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-01-13T08:13:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1aae452-50e5-4fda-b043-7e89c44e9ebd'	System	13 Jan 2021 14:14:28
User entered 'Yes (Y)'	System	13 Jan 2021 14:14:28

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-01-13T08:13:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1aae452-50e5-4fda-b043-7e89c44e9ebd'	System	13 Jan 2021 14:14:28
User entered 'No (N)'	System	13 Jan 2021 14:14:28

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-01-13T08:13:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1aae452-50e5-4fda-b043-7e89c44e9ebd'	System	13 Jan 2021 14:14:28
User entered 'No (N)'	System	13 Jan 2021 14:14:28

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-01-13T08:13:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1aae452-50e5-4fda-b043-7e89c44e9ebd'	System	13 Jan 2021 14:14:28
User entered 'Yes (Y)'	System	13 Jan 2021 14:14:28

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Please 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 (1db0398f97ba671b)', Time: '2021-01-13T08:14:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1aae452-50e5-4fda-b043-7e89c44e9ebd'	System	13 Jan 2021 14:14:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 14:14:28

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-01-13T08:14:21', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1aae452-50e5-4fda-b043-7e89c44e9ebd' User entered '13 Jan 2021 08:14:21'	System	13 Jan 2021 14:14:28
	System	13 Jan 2021 14:14:28

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-01-18T09:29:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '10dd8f3d-00a6-4e25-9a8b-783e6d7f22be'	System	18 Jan 2021 15:29:31
User entered 'No (N)'	System	18 Jan 2021 15:29:31

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-01-18T09:29:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '10dd8f3d-00a6-4e25-9a8b-783e6d7f22be'	System	18 Jan 2021 15:29:31
User entered 'No (N)'	System	18 Jan 2021 15:29:31

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-01-18T09:29:28', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '10dd8f3d-00a6-4e25-9a8b-783e6d7f22be'	System	18 Jan 2021 15:29:31
User entered '18 Jan 2021 09:29:28'	System	18 Jan 2021 15:29:31

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-01-26T06:18:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8dc42829-dc75-4d23-b762-045f9bbbce71'	System	26 Jan 2021 12:18:30
User entered 'No (N)'	System	26 Jan 2021 12:18:30



US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-01-26T06:18:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8dc42829-dc75-4d23-b762-045f9bbbce71'	System	26 Jan 2021 12:18:30
User entered 'No (N)'	System	26 Jan 2021 12:18:30

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-01-26T06:18:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8dc42829-dc75-4d23-b762-045f9bbbce71'	System	26 Jan 2021 12:18:30
User entered '26 Jan 2021 06:18:26'	System	26 Jan 2021 12:18:30

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:34:03

US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-02-01T12:00:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '17a4fe42-79c7-4311-947c-74eb917f727c'	System	01 Feb 2021 18:02:52
User entered 'No (N)'	System	01 Feb 2021 18:02:52

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-02-01T12:01:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '17a4fe42-79c7-4311-947c-74eb917f727c'	System	01 Feb 2021 18:02:52
User entered 'No (N)'	System	01 Feb 2021 18:02:52

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-02-01T12:01:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '17a4fe42-79c7-4311-947c-74eb917f727c'	System	01 Feb 2021 18:02:52
User entered '01 Feb 2021 12:01:13'	System	01 Feb 2021 18:02:52



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-02-08T12:24:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '04bf2fcc-74e7-4319-ba60-a6ee4fff44fb'	System	08 Feb 2021 18:25:16
User entered 'No (N)'	System	08 Feb 2021 18:25:16

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-02-08T12:24:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '04bf2fcc-74e7-4319-ba60-a6ee4fff44fb'	System	08 Feb 2021 18:25:16
User entered 'No (N)'	System	08 Feb 2021 18:25:16

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-02-08T12:25:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '04bf2fcc-74e7-4319-ba60-a6ee4fff44fb'	System	08 Feb 2021 18:25:16
User entered '08 Feb 2021 12:25:09'	System	08 Feb 2021 18:25:16

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-02-15T13:33:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'b1cd3ab3-5511-4556-88aa-a97846d6bcb8'	System	15 Feb 2021 19:34:02
User entered 'No (N)'	System	15 Feb 2021 19:34:02

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-02-15T13:33:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'b1cd3ab3-5511-4556-88aa-a97846d6bcb8'	System	15 Feb 2021 19:34:02
User entered 'No (N)'	System	15 Feb 2021 19:34:02

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-02-15T13:33:59', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'b1cd3ab3-5511-4556-88aa-a97846d6bcb8'	System	15 Feb 2021 19:34:02
User entered '15 Feb 2021 13:33:59'	System	15 Feb 2021 19:34:02

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-02-20T07:23:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ff1f10a7-1a29-4ec9-9659-d2063b52c228'	System	20 Feb 2021 13:24:09
User entered 'No (N)'	System	20 Feb 2021 13:24:09



US3362285

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-02-20T07:24:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ff1f10a7-1a29-4ec9-9659-d2063b52c228'	System	20 Feb 2021 13:24:09
User entered 'No (N)'	System	20 Feb 2021 13:24:09

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-02-20T07:24:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ff1f10a7-1a29-4ec9-9659-d2063b52c228'	System	20 Feb 2021 13:24:09
User entered '20 Feb 2021 07:24:09'	System	20 Feb 2021 13:24:09

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-02-27T00:13:07-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1fde4e5d-14b3-47f1-8c16-e2002040c6a4'	System	27 Feb 2021 06:13:51
User entered 'No (N)'	System	27 Feb 2021 06:13:51

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-02-27T00:13:28-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1fde4e5d-14b3-47f1-8c16-e2002040c6a4'	System	27 Feb 2021 06:13:51
User entered 'No (N)'	System	27 Feb 2021 06:13:51

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-02-27T00:13:34-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1fde4e5d-14b3-47f1-8c16-e2002040c6a4'	System	27 Feb 2021 06:13:51
User entered '27 Feb 2021 00:13:34'	System	27 Feb 2021 06:13:51



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-03-06T07:00:07-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0770af5f-ecf6-4311-a6ba-56501ad6f9ae'	System	06 Mar 2021 13:00:29
User entered 'No (N)'	System	06 Mar 2021 13:00:29

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-03-06T07:00:11-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0770af5f-ecf6-4311-a6ba-56501ad6f9ae'	System	06 Mar 2021 13:00:29
User entered 'No (N)'	System	06 Mar 2021 13:00:29

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-03-06T07:00:22-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0770af5f-ecf6-4311-a6ba-56501ad6f9ae' User entered '06 Mar 2021 07:00:22'	System	06 Mar 2021 13:00:29
	System	06 Mar 2021 13:00:29

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-03-13T16:41:23-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '08abd782-5b6a-4955-9b95-afb03bc1788b'	System	13 Mar 2021 22:41:54
User entered 'No (N)'	System	13 Mar 2021 22:41:54

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-03-13T16:41:28-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '08abd782-5b6a-4955-9b95-afb03bc1788b'	System	13 Mar 2021 22:41:54
User entered 'No (N)'	System	13 Mar 2021 22:41:54

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-03-13T16:41:33-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '08abd782-5b6a-4955-9b95-afb03bc1788b'	System	13 Mar 2021 22:41:54
User entered '13 Mar 2021 16:41:33'	System	13 Mar 2021 22:41:54

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-03-20T01:56:17-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '902357de-8a1b-4adc-8b70-1fdc81de8173'	System	20 Mar 2021 06:56:38
User entered 'No (N)'	System	20 Mar 2021 06:56:38



US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-03-20T01:56:27-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '902357de-8a1b-4adc-8b70-1fdc81de8173'	System	20 Mar 2021 06:56:38
User entered 'No (N)'	System	20 Mar 2021 06:56:38

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-03-20T01:56:31-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '902357de-8a1b-4adc-8b70-1fdc81de8173' User entered '20 Mar 2021 01:56:31'	System	20 Mar 2021 06:56:38
	System	20 Mar 2021 06:56:38

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-03-27T13:53:10-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '70636299-5570-41ef-8dc1-e6c8d3f5d69f'	System	27 Mar 2021 18:53:28
User entered 'No (N)'	System	27 Mar 2021 18:53:28

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-03-27T13:53:20-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '70636299-5570-41ef-8dc1-e6c8d3f5d69f'	System	27 Mar 2021 18:53:28
User entered 'No (N)'	System	27 Mar 2021 18:53:28

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-03-27T13:53:24-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '70636299-5570-41ef-8dc1-e6c8d3f5d69f' User entered '27 Mar 2021 13:53:24'	System	27 Mar 2021 18:53:28
	System	27 Mar 2021 18:53:28



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-04-03T02:55:18-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0235ac75-f367-4750-9b67-ebdce5b3592c' User entered 'No (N)'	System	03 Apr 2021 07:55:35
	System	03 Apr 2021 07:55:35

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-04-03T02:55:27-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0235ac75-f367-4750-9b67-ebdce5b3592c'	System	03 Apr 2021 07:55:35
User entered 'No (N)'	System	03 Apr 2021 07:55:35

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-04-03T02:55:32-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0235ac75-f367-4750-9b67-ebdce5b3592c' User entered '03 Apr 2021 02:55:32'	System	03 Apr 2021 07:55:35
	System	03 Apr 2021 07:55:35

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-04-10T10:03:56-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8ea0742e-2b7f-428b-b5ab-a21d7f7a05fd' User entered 'No (N)'	System	10 Apr 2021 15:04:24
	System	10 Apr 2021 15:04:24

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-04-10T10:04:06-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8ea0742e-2b7f-428b-b5ab-a21d7f7a05fd' User entered 'No (N)'	System	10 Apr 2021 15:04:24
	System	10 Apr 2021 15:04:24

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-04-10T10:04:18-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8ea0742e-2b7f-428b-b5ab-a21d7f7a05fd' User entered '10 Apr 2021 10:04:18'	System	10 Apr 2021 15:04:24
	System	10 Apr 2021 15:04:24

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-04-17T08:53:20-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1f335c3f-5199-43a5-902b-c62fb1facb59' User entered 'No (N)'	System	17 Apr 2021 13:53:45
	System	17 Apr 2021 13:53:45



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-04-17T08:53:32-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1f335c3f-5199-43a5-902b-c62fb1facb59'	System	17 Apr 2021 13:53:45
User entered 'No (N)'	System	17 Apr 2021 13:53:45

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-04-17T08:53:36-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1f335c3f-5199-43a5-902b-c62fb1facb59' User entered '17 Apr 2021 08:53:36'	System	17 Apr 2021 13:53:45
	System	17 Apr 2021 13:53:45

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-04-24T13:03:19-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0bda3abc-f5f2-4c2e-9b2d-829f7075ef42'	System	24 Apr 2021 18:03:37
User entered 'No (N)'	System	24 Apr 2021 18:03:37

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-04-24T13:03:27-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0bda3abc-f5f2-4c2e-9b2d-829f7075ef42'	System	24 Apr 2021 18:03:37
User entered 'No (N)'	System	24 Apr 2021 18:03:37

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-04-24T13:03:32-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0bda3abc-f5f2-4c2e-9b2d-829f7075ef42'	System	24 Apr 2021 18:03:37
User entered '24 Apr 2021 13:03:32'	System	24 Apr 2021 18:03:37



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[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 (1db0398f97ba671b)', Time: '2021-05-01T03:34:03-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '64c5a5ff-e489-498e-aaf9-6246bb995b8f' User entered 'No (N)'	System	01 May 2021 08:34:29
	System	01 May 2021 08:34:29

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

Have you been exposed to someone with 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 (1db0398f97ba671b)', Time: '2021-05-01T03:34:19-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '64c5a5ff-e489-498e-aaf9-6246bb995b8f'	System	01 May 2021 08:34:29
User entered 'No (N)'	System	01 May 2021 08:34:29

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-05-01T03:34:24-05:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '64c5a5ff-e489-498e-aaf9-6246bb995b8f' User entered '01 May 2021 03:34:24'	System	01 May 2021 08:34:29
	System	01 May 2021 08:34:29

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:34:03



**US3362285**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 10:34:03

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 10:34:03



US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:03

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:34:03

US3362285

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 10:34:03



**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 10:34:03

**US3362285**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:16:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:03
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 10:34:03

US3362285

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:16:03**

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)	26 Apr 2021 06:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-03-06T07:00:47-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '6d785e1e-ccff-44c8-b66b-a4c2f58bad32'	System	06 Mar 2021 13:01:12
User entered 'No (N)'	System	06 Mar 2021 13:01:12

US3362285

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:16:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2021-03-06T07:01:04-06:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '6d785e1e-ccff-44c8-b66b-a4c2f58bad32'	System	06 Mar 2021 13:01:12
User entered '06 Mar 2021 07:01:04'	System	06 Mar 2021 13:01:12



US3362285

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:28:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 21:04:18

US3362285

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:28:49
User entered '14 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 21:04:18

US3362285

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:28:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:04:18

US3362285

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:28:49
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 21:04:18

US3362285

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:28:49
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Feb 2021 22:57:26

US3362285

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:48:58
User entered 'I'	System	19 Feb 2021 22:57:26

US3362285

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:25

US3362285

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '18 Jan 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:25



US3362285

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Contact Made (CONTACT MADE)'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:25

US3362285

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:58:25

US3362285

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:31

**US3362285**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:16:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User entered 'I'	System	19 Feb 2021 22:58:31

**US3362285**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:16:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:45

US3362285

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '18 Feb 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:45

US3362285

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Contact Made (CONTACT MADE)'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:45

US3362285

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:58:45



US3362285

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Feb 2021 22:58:49

US3362285

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User entered 'I'	System	19 Feb 2021 22:58:49

US3362285

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 15:37:24

US3362285

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 15:37:24

US3362285

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Mar 2021 15:37:24

US3362285

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:24

US3362285

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 15:37:28

US3362285

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:08:38
User entered 'I'	System	18 Mar 2021 15:37:28



US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 17:46:04

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 17:46:04

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[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 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Jan 2021 17:46:04

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 17:46:04

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '15 Jan 2021' reason for change: Data Entry Error	Amy Thomassie (b) (4)	19 Feb 2021 02:19:16
User entered '06 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[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 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:16:02

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
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 15:16:02



US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 09:43:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 09:43:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered empty.	System	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered empty.	System	15 Jan 2021 17:46:32

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 17:46:57



US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 17:46:57

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '08:53'	(b) (4), (b) (6)	15 Jan 2021 17:46:57

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered '15 Jan 2021 08:53'	System	15 Jan 2021 17:46:57

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 17:47:11

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 17:47:11

US3362285

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '08:56'	(b) (4), (b) (6)	15 Jan 2021 17:47:11

**US3362285**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:16:03**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:27:29
User entered '15 Jan 2021 08:56'	System	15 Jan 2021 17:47:11

US3362285

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:16:03**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:42
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:50:55
Query 'Per DM CLR: Per Safety Follow-up Diary Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Subject reported seeing healthcare provider following syncope and diagnosis with heart block in January. AE, con med, and con procedure logs updated' (Site from DM).	Alexandra Caillouet (b) (4)	07 Apr 2021 21:33:34
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 11:00:04
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	13 Mar 2021 22:21:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 20:22:11
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:16:26



US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 00:22:39
User entered		
'USA-US112-2020-mRNA-1273-P301000011'	System	24 Nov 2020 00:22:32
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 00:22:32

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Nov 2020 20:29:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 20:29:14
Data point term sent to Coder	System	20 Nov 2020 20:28:37
User entered 'Cerebrovascular Accident'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '16 Nov 2020'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

**US3362285**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:16:03**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 20:28:37



US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '18 Nov 2020'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

**US3362285**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:16:03**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 20:28:37

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'I'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'I'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '16 Nov 2020'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '18 Nov 2020'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
User entered 'Not Related (NOT RELATED)'	(b) (4) Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 20:28:37

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
User entered 'Not Related (NOT RELATED)'	(b) (4) Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 20:28:37

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 20:28:37

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

None

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '1'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 20:28:37

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	20 Nov 2020 20:28:37
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:21:44
User entered 'Patient contacted site -sent to ER on night of 16Nov2020 for difficulty speaking and diagnosed with cerebrovascular accident. admitted to hospital 16Nov-18Nov2020; stated only new medication was full dose Asprin 325mg right now; will come to sign medical release and update accordingly, has follow up with cardiologist reports cause of CVA left coronary artery occlusion - will confirm with medical records.'	(b) (4) Crystal Rowell (b) (4)	20 Nov 2020 20:28:37

**US3362285**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 20:28:37

**US3362285**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 20:28:37

**US3362285**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 20:28:37

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncopal attack - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 16:35:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 16:35:06
	(b) (4)	
Data point term sent to Coder	System	29 Mar 2021 16:34:44
User entered 'Syncopal episode'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '5 Jan 2021'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User entered empty.	System	29 Mar 2021 16:34:18

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '5 Jan 2021'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User entered empty.	System	29 Mar 2021 16:34:18



US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Alexandra Caillouet	07 Apr 2021 21:29:41
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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).	(b) (4), (b) (6)	08 Apr 2021 21:51:14
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	07 Apr 2021 21:29:47
User entered '0' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	07 Apr 2021 21:29:41
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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).	(b) (4), (b) (6)	05 Apr 2021 05:35:41
User entered '1'	Alexandra Caillouet (b) (4)	29 Mar 2021 16:34:18

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:34:18
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User entered '0'	System	29 Mar 2021 16:34:18

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28
User entered '1'	System	29 Mar 2021 16:34:18

US3362285

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:28



US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Atrioventricular block, LLT: Heart block - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 21:31:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 21:31:26
	(b) (4)	
Data point term sent to Coder System		07 Apr 2021 21:31:13
User entered 'Heart Block'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '5 Jan 2021'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User entered empty.	System	07 Apr 2021 21:30:33



US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '25 Feb 2021'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User entered empty.	System	07 Apr 2021 21:30:33

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'I'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	



US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:44:12
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 21:30:33
	(b) (4)	

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User entered '0'	System	07 Apr 2021 21:30:33

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32
User entered '1'	System	07 Apr 2021 21:30:33

US3362285

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:13:32

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 17:16:03**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:16:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:19:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:19:55
Data point term sent to Coder	System	30 Sep 2020 15:18:56
User entered 'LOSARTAN/HYDROCHLOROTHIAZIDE'	(b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '100/25'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2001'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:17:58

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:17:58

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:19:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:19:54
Data point term sent to Coder	System	30 Sep 2020 15:18:57
User entered 'ZETIA'	(b) (4), (b) (6)	30 Sep 2020 15:18:43



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'HYPERLIPIDEMIA'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '10'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:18:43

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:18:43



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:18:43

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:20:56
Data point term sent to Coder	System	30 Sep 2020 15:19:58
User entered 'GLIPIZIDE'	(b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'DIABETES TYPE II'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
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)	02 Dec 2020 20:20:08
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).	(b) (4), (b) (6)	02 Dec 2020 15:41:15
User entered '40' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 15:39:11
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)	30 Nov 2020 08:59:45
User entered '4'	(b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2001'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 17:52:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'un UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 17:52:55
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:19:33



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User entered '2'	System	30 Sep 2020 15:19:33

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User entered '1'	System	30 Sep 2020 15:19:33

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:14
User entered '804 (804)'	System	30 Sep 2020 15:19:33

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Sep 2020 15:21:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:21:56
Data point term sent to Coder	System	30 Sep 2020 15:21:00
User entered 'TRULICITY'	(b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'DIABETES TYPE II'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '1.5'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'every week (QS)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:20:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	30 Sep 2020 15:20:38

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Sep 2020 15:22:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:22:54
Data point term sent to Coder	System	30 Sep 2020 15:22:04
User entered 'JARDIANCE'	(b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'DIABETES TYPE II'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '25'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:21:21

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:21:21

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
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: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Sep 2020 15:23:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:23:48
Data point term sent to Coder	System	30 Sep 2020 15:23:06
User entered 'TAMSULOSIN'	(b) (4), (b) (6)	30 Sep 2020 15:22:13



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'BENIGN PROSTATE HYPERTROPHY'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0.4'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:22:13

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:22:13



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:22:13

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
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.	(b) (4) Coder Import (b) (4)	30 Sep 2020 15:23:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:23:49
Data point term sent to Coder	System	30 Sep 2020 15:23:07
User entered 'FINASTERIDE'	(b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'BENIGN PROSTATE HYPERTROPHY'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '5'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:22:54



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:22:54

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:22:54

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 16:16:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	11 Feb 2021 16:16:53
Data point term sent to Coder	System	11 Feb 2021 16:01:49
Data point term sent to Coder	System	11 Feb 2021 16:00:48
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 16:00:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 15:37:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	02 Dec 2020 15:37:03
Data point term sent to Coder	System	02 Dec 2020 15:35:44
Coding entries removed.	(b) (4), (b) (6)	02 Dec 2020 15:35:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 15:36:56

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'MOBIC'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	30 Sep 2020 15:36:56  30 Sep 2020 15:25:13 30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:56:14
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 16:00:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 16:00:52
User entered 'GENERALIZED ARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 16:00:52
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 16:00:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered by data change (Site from DM).	System	11 Feb 2021 16:00:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 16:00:17
Comment added 'Generalized Arthritis is part of patient's medical history. It is not an AE. Med History has now been updated.'	(b) (4), (b) (6)	11 Feb 2021 15:59:16
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:12:28
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 09:20:32

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:35:44
User entered 'Generalized Arthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 15:35:38
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 09:00:57
User entered 'ANXIETY'	(b) (4), (b) (6)	30 Sep 2020 15:24:57



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '15'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 16:00:06
User entered 'once daily (QD)'	(b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 17:53:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 17:53:55
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:57

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User entered empty.	System	11 Feb 2021 16:00:06
User entered '1'	System	30 Sep 2020 15:24:57

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User entered empty.	System	11 Feb 2021 16:00:06
User entered '1'	System	30 Sep 2020 15:24:57

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:44
User entered empty.	System	11 Feb 2021 16:00:06
User entered '804 (804)'	System	30 Sep 2020 15:24:57

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 15:27:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 15:27:50
Data point term sent to Coder	System	30 Sep 2020 15:26:14
User entered 'ASPIRIN'	(b) (4), (b) (6)	30 Sep 2020 15:25:31



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User closed query 'Per DM CLR: Please review response as cardiac health/wellness are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 19:01:06
Query 'Per DM CLR: Please review response as cardiac health/wellness are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:43:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 15:43:07
User opened query 'Per DM CLR: Please review response as cardiac health/wellness are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 09:01:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'CARDIAC HEALTH'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '81'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 17:54:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 17:54:29
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:31

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User entered '1'	System	30 Sep 2020 15:25:31

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User entered '1'	System	30 Sep 2020 15:25:31



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:48
User entered '804 (804)'	System	30 Sep 2020 15:25:31

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
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)	13 Nov 2020 16:39:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 16:39:49
Data point term sent to Coder	System	13 Nov 2020 16:38:33
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'INFLUENZA PREVENTION'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0.5'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:37:41



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User entered empty.	System	13 Nov 2020 16:37:41

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User entered empty.	System	13 Nov 2020 16:37:41

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:52
User entered empty.	System	13 Nov 2020 16:37:41

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:27:47
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' answered with 'Protocol Deviation logged.' (Site from DM).	Alexandra Caillouet (b) (4)	15 Dec 2020 20:03:33
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:56:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:39:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:39:51
Data point term sent to Coder	System	13 Nov 2020 16:38:33
User entered 'PNEUMONIA VACCINE'	(b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'PNEUMONIA PREVENTION'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0.5'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:38:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User entered empty.	System	13 Nov 2020 16:38:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User entered empty.	System	13 Nov 2020 16:38:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:54:57
User entered empty.	System	13 Nov 2020 16:38:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 23:52:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:52:11
Data point term sent to Coder	System	24 Nov 2020 21:51:55
User entered 'clopidogrel'	Crystal Rowell (b) (4) (b) (4)	24 Nov 2020 21:51:30

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered 'prevention of cerebrovascular accident'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered '75'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered 'mg (mg)'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered 'once daily (QD)'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered '24 Nov 2020'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:18:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 22:18:31
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	24 Nov 2020 22:18:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 21:51:30
User entered empty.	Crystal Rowell (b) (4)	24 Nov 2020 21:51:30
	(b) (4)	

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:51:30

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:51:30

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:51:30

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 18:14:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 18:14:56
Data point term sent to Coder	System	15 Jan 2021 17:57:47
User entered 'aspirin'	(b) (4), (b) (6)	15 Jan 2021 17:57:22



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'cerebrovascular accident'	(b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '325'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '16 Nov 2020'	(b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 17:57:22

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User entered '1'	System	15 Jan 2021 17:57:22

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User entered '1'	System	15 Jan 2021 17:57:22



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:06
User entered '804 (804)'	System	15 Jan 2021 17:57:22

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:59:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:59:55
Data point term sent to Coder	System	15 Jan 2021 17:58:48
User entered 'aspirin'	(b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'cerebrovascular accident'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '81'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:58:38



**US3362285**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 17:58:38

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 17:58:38

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 16:48:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 16:48:04
Data point term sent to Coder	System	29 Mar 2021 16:46:59
User entered 'Glimepiride'	Alexandra Caillouet (b) (4)	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	Alexandra Caillouet	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Diabetes Type II'	Alexandra Caillouet	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '4'	Alexandra Caillouet (b) (4)	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	Alexandra Caillouet (b) (4)	29 Mar 2021 16:46:11



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	Alexandra Caillouet (b) (4)	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'twice daily (BID)'	(b) (4) Alexandra Caillouet	29 Mar 2021 16:46:11
	(b) (4)	

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) Alexandra Caillouet	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	Alexandra Caillouet	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '16 Nov 2020'	Alexandra Caillouet	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	Alexandra Caillouet (b) (4)	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:27:52
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	29 Mar 2021 16:46:11



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'un Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:27:52
User entered empty.	Alexandra Caillouet	29 Mar 2021 16:46:11
	(b) (4)	

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	Alexandra Caillouet	29 Mar 2021 16:46:11

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User entered '2'	System	29 Mar 2021 16:46:11

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User entered '1'	System	29 Mar 2021 16:46:11

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:29:08
User entered '804 (804)'	System	29 Mar 2021 16:46:11

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 14:30:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:30:42
Data point term sent to Coder	System	07 Apr 2021 14:29:55
User entered 'repatha'	(b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '140'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'every other week'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:29:03

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:29:03

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 09:25:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:25:44
Data point term sent to Coder	System	07 Apr 2021 16:05:52
User entered 'Vancomycin'	(b) (4), (b) (6)	07 Apr 2021 16:05:23



US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Pre-OP Surgery for Pace maker placement'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:23

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User entered empty.	System	07 Apr 2021 16:05:23

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User entered empty.	System	07 Apr 2021 16:05:23



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:55:11
User entered empty.	System	07 Apr 2021 16:05:23

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
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.	(b) (4) Coder Import (b) (4)	07 Apr 2021 16:32:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:32:34
Data point term sent to Coder	System	07 Apr 2021 16:31:29
User entered 'omeprazole'	(b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Gastroesophageal reflux disease'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '40'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:31:28



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 16:31:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 16:31:28

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: VARDENAFIL HYDROCHLORIDE, PRODUCTSYNONYM: LEVITRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 16:33:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 16:33:39
Data point term sent to Coder	System	07 Apr 2021 16:32:29
User entered 'Levitra'	(b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Erectile Dysfunction'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '20'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28



US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:32:28

**US3362285**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 16:32:28

US3362285

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:16:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 16:32:28

US3362285

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:16:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:39:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:16:42

US3362285

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:16:03**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:40:49

US3362285

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Pacemaker'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:40:49



US3362285

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:40:49

US3362285

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:16:03**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 01:00:35
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:40:49

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'USA-US112-2020-MRNA-1273-P301000011'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Yes (Y)'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Yes (Y)'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Yes (Y)'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32



**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Jordan'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Whatley'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered '5326 O'donovan dr'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'baton rouge'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered '70808'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'US'	(b) (4) System	24 Nov 2020 00:23:02



**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 00:23:02

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'USA-US112-2020-MRNA-1273-P301000011'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Yes (Y)'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Yes (Y)'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Yes (Y)'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32



US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'No (N)'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Jordan'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'Whatley'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered '5326 O'donovan dr'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered 'baton rouge'	System	24 Nov 2020 00:22:32

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:22:55
User entered '70808'	System	24 Nov 2020 00:22:32

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'US'	(b) (4) System	24 Nov 2020 00:23:02

**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:16:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 00:23:02



**US3362285**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:16:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered '24/Nov/2020 00:23'	(b) (4) System	24 Nov 2020 00:23:02

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	25 Apr 2021 01:40:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:23:02