

US3612060 (Prod: University of Texas- Galveston)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:09:47

All time stamps listed in this document are displayed in GMT

US3612060

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 16:20:02

Generated On: 10 Jun 2021 09:09:47

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Participant ID

US3612060

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

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US3612060

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 20:06:35

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	30 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 checked="" type="radio"/> No <input type="radio"/>
If Yes, previous participant number	US3612002
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	MITRAL VALVE REPAIR
Start date (dd MMM yyyy)	28 MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	28 MAY 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAY 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	PROSTATECTOMY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	MITRAL VALVE REGURGITATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	28 MAY 2017
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	MAY 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	DEGENERATIVE DISC DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	RIGHT SHOULDER PAIN
Start date (dd MMM yyyy)	UN JUN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Apr 2021 21:34:35

Generated On: 10 Jun 2021 09:09:47

Condition	RIGHT SHOULDER ARTHRITIS
Start date (dd MMM yyyy)	UN JUN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3612060

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	30 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:24 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:24
Height ( <i>xxx.x</i> )	68.5 in
Weight ( <i>xxx.x</i> )	184 lb
BMI ( <i>xxx.x</i> )	27.62782 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

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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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 20:06:35

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 20:06:44

Generated On: 10 Jun 2021 09:09:47

What was the date of randomization? (dd MMM yyyy) 30 SEP 2020

What was the participant's randomization number? 191379

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

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)	30 SEP 2020
Time of assessment (00:00-23:59)	09:24 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:24
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:38
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:06:44

Generated On: 10 Jun 2021 09:09:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 20:06:44

Generated On: 10 Jun 2021 09:09:47

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 11:05 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 11:05

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:06:44

Generated On: 10 Jun 2021 09:09:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	09:55 (24 HR)
Collection date and time (derived)	30 SEP 2020 09:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:01	30 SEP 2020 10:01
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**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

98.2 °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

30 SEP 2020 11:32

PC Open Date & Time

30 SEP 2020 11:25

PC Close Date & Time

30 SEP 2020 13:55

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	30 SEP 2020 18:09
PC Open Date & Time	30 SEP 2020 14:50
PC Close Date & Time	01 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

01 OCT 2020 18:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 14:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

03 OCT 2020 22:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.7 °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

04 OCT 2020 19:25

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PC Open Date & Time

04 OCT 2020 12:00

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PC Close Date & Time

05 OCT 2020 11:59

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US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**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

05 OCT 2020 17:30

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59



US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 17:47

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**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

30 SEP 2020 11:31

PC Open Date & Time

30 SEP 2020 11:25

PC Close Date & Time

30 SEP 2020 13:55

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**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

30 SEP 2020 18:05

PC Open Date & Time

30 SEP 2020 14:50

PC Close Date & Time

01 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**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

01 OCT 2020 18:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**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

02 OCT 2020 14:40

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**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

03 OCT 2020 22:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**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

04 OCT 2020 19:26

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**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

05 OCT 2020 17:31

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59



US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**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

06 OCT 2020 17:47

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**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 ☐

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 11:33
PC Open Date & Time	30 SEP 2020 11:25
PC Close Date & Time	30 SEP 2020 13:55

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**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 ☐

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 18:06
PC Open Date & Time	30 SEP 2020 14:50
PC Close Date & Time	01 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 18:02
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 14:41
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**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

EAB) (1725)

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US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 22:04
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

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  
EAB) (1725)

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US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 19:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:31
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**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 ☒



US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 17:47
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3612060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:34

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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



US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

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)	28 OCT 2020
Time of assessment (00:00-23:59)	08:31 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 08:31
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

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)	28 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 10:10
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3612060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3612060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

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) 28 OCT 2020

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 28 OCT 2020 09:38

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

US3612060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

28 OCT 2020 08:40

US3612060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Collection date (dd MMM yyyy)			28 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:48	28 OCT 2020 08:48
Nasopharyngeal Swab 2	No		

US3612060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 10:12

PC Open Date & Time

28 OCT 2020 09:58

PC Close Date & Time

28 OCT 2020 12:28



US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**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 97.8 °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	28 OCT 2020 15:45
PC Open Date & Time	28 OCT 2020 13:23
PC Close Date & Time	29 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**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

96.8 °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

29 OCT 2020 18:03

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

31 OCT 2020 16:03

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 18:50

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 14:48

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 NOV 2020 15:38

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**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

28 OCT 2020 10:12

PC Open Date & Time

28 OCT 2020 09:58

PC Close Date & Time

28 OCT 2020 12:28



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**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

28 OCT 2020 15:46

PC Open Date & Time

28 OCT 2020 13:23

PC Close Date & Time

29 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**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

29 OCT 2020 18:03

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**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

30 OCT 2020 12:23

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**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

31 OCT 2020 16:02

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**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

01 NOV 2020 18:50

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**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

02 NOV 2020 14:49

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**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

03 NOV 2020 15:39

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**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 ☐



US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

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

No ☒

Yes ☐

PC Time stamp	28 OCT 2020 10:13
PC Open Date & Time	28 OCT 2020 09:58
PC Close Date & Time	28 OCT 2020 12:28

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**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 ☐

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

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

No ☒

Yes ☐

PC Time stamp	28 OCT 2020 15:47
PC Open Date & Time	28 OCT 2020 13:23
PC Close Date & Time	29 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**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 ☒

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 18:03
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 12:24
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**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 ☒



US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 16:02
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**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 ☒

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 18:51
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**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 ☒

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 14:49
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**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 ☒

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 15:39
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3612060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3612060

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 DEC 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

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	08:46 (24 HR)
Vital Signs Date and Time (derived)	1 DEC 2020 08:46
Temperature ( <i>xxx.x</i> )	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3612060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 DEC 2020

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



US3612060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 DEC 2020
Collection time (00:00-23:59)	08:48 (24 HR)
Collection date and time (derived)	1 DEC 2020 08:48

US3612060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:45

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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 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 DEC 2020 09:30:37
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 08:03:29
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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	11 DEC 2020 09:30:00
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 17:57:24

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

25 DEC 2020 10:48:51

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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	01 JAN 2021 08:12:32
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59



US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

08 JAN 2021 09:35:34

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 07:45:46

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

22 JAN 2021 15:58:25

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 08:56:00

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 08:18:03

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

12 FEB 2021 14:49:10

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 08:14:09

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 13:19:56

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59



US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

05 MAR 2021 13:15:41

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 07:53:44

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

19 MAR 2021 15:17:57

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 08:05:10

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

03 APR 2021 07:21:05

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 08:20:57

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 15:59:10

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

23 APR 2021 12:23:28

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59



US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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

30 APR 2021 08:08:30

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 222

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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="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"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 236

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	11 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	20 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59
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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 376

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59
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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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="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"/>



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2021 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59
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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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="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"/>



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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="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"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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"/>



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUL 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 733

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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="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"/>

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 747

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 754

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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25 OCT 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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



**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**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 ☐

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2022 23:59

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US3612060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:47

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

**US3612060**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

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

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[Patient Cloud Close Date & Time](#)

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06 DEC 2022 23:59

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US3612060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:09:47

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		05 MAR 2021 13:16:01



US3612060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:06:35

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3612060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3612060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

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.*

US3612060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 APR 2021
Collection time (00:00-23:59)	08:36 (24 HR)
Collection date and time (derived)	13 APR 2021 08:36

US3612060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3612060**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3612060**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3612060

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:09:47

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"/>



**US3612060**

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

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

**Generated On: 10 Jun 2021 09:09:47**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3612060

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

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

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

Visit date (dd MMM yyyy)	06 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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US3612060

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

Form: Unblinding

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	06 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3612060

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3612060

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	06 JAN 2021
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 11:09
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	071 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	077 mmHg
Diastolic Blood Pressure units	MMHG

US3612060

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	06 JAN 2021
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 11:52
Temperature (xxx.x)	098.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	079 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3612060

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

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

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.*

US3612060

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

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 06 JAN 2021

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 06 JAN 2021 11:20

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



US3612060

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 JAN 2021

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

06 JAN 2021 10:40

US3612060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 JAN 2021
Collection time (00:00 - 23:59)	10:46
Collection Date and Time (derived)	06 JAN 2021 10:46

US3612060

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

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3612060

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

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)	2 FEB 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 11:05
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

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)	2 FEB 2021
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 11:59
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG



US3612060

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

2 FEB 2021

---

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

---

US3612060

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 11:25 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 11:25

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

US3612060

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612060

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:20:04

Generated On: 10 Jun 2021 09:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612060

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3612060

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3612060

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

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.*



US3612060

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	10 MAR 2021
Collection time ( <i>00:00-23:59</i> )	14:17 (24 HR)
Collection date and time (derived)	10 MAR 2021 14:17

US3612060

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 16:15:50

Generated On: 10 Jun 2021 09:09:47

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3612060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:56:40

Generated On: 10 Jun 2021 09:09:47

AEID

Adverse event

RIGHT CARPAL TUNNEL

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:56:40

Generated On: 10 Jun 2021 09:09:47

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	_____

US3612060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 20:56:40

Generated On: 10 Jun 2021 09:09:47

AEID	USA-US129-2021-MRNA-1273-P30 1000005
Adverse event	TOTAL SHOULDER ARTHROPLASTY
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)	31 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	02 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 20:56:40

Generated On: 10 Jun 2021 09:09:47

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	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	

US3612060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 20:56:40

Generated On: 10 Jun 2021 09:09:47

---

PATIENT REPORTS HAVING  
ELECTIVE RIGHT SHOULDER  
SURGERY FOR ROTATOR CUFF  
REPAIR D/T MEDICAL HISTORY  
OF RIGHT SHOULDER PAIN  
SECONDARY TO ARTHRITIS  
SINCE JUNE 2016. HE NOTES 2  
NIGHT STAY IN THE HOSPITAL  
FOR POST-OPERATIVE  
RECOVERY W/O ANY  
COMPLICATIONS. PT  
DISCHARGED HOME ON ORAL  
TRAMADOL FOR PAIN. SITE  
NOT AWARE OF ANY COVID-19  
TESTING DONE.

---

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

---

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

---

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

Yes ☒

No ☐

---

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

---



US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication STROKE PREVENTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication AMLODIPINE/ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5/20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

	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 2000	
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"/>

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication KNEE AND BACK PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

	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"/>

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication FLUTICASONE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication AZELASTINE HCL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 137

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication CIALIS

Prophylaxis Yes ☐  
No ☒

Indication PROSTATECTOMY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication CENTRUM SILVER ADULTS 50 +

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication OMEGA 3-6-9

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication ALLERGY SHOTS

Prophylaxis Yes ☒  
No ☐

Indication SEASONAL ALLERGIES

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HAND PAIN/CARPAL  
TUNNEL

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT SHOULDER PAIN  
POST-OPERATIVE ROTATOR  
CUFF REPAIR

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 16:20:03

Generated On: 10 Jun 2021 09:09:47

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 14 Apr 2021 14:51:28

Generated On: 10 Jun 2021 09:09:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 DEC 2020	RIGHT CARPAL TUNNEL SURGERY	Medical History	
29 DEC 2020	EMG (ELECTROMYOGRAPHIC NERVE STUDY)	Diagnostic	
31 MAR 2021	RIGHT ROTATOR CUFF REPAIR	Medical History	



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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:09:47

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:09:47

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 ☐

US3612060

Folder: SAE USA-US129-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 20:27:22

Generated On: 10 Jun 2021 09:09:47

SAEID	USA-US129-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3612060

Folder: SAE USA-US129-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 20:27:22

Generated On: 10 Jun 2021 09:09:47

SAEID	USA-US129-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/APR/2021 14:51
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

US3612060

Folder: SAE USA-US129-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 20:27:22

Generated On: 10 Jun 2021 09:09:47

SAEID	USA-US129-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/APR/2021 13:22
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

US3612060

Folder: SAE USA-US129-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 20:27:22

Generated On: 10 Jun 2021 09:09:47

SAEID	USA-US129-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/APR/2021 10:54
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

US3612060 (Prod: University of Texas- Galveston)

**US3612060**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:09:47**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:52:18
User entered 'US3612060'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	30 Sep 2020 14:02:58



**US3612060**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:53:07
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:15:09

**US3612060**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:53:07
User entered '30 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	30 Sep 2020 14:02:59

**US3612060**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:53:07
User entered 'Clinic (Clinic)'	Amy McMahan (b) (4)	30 Sep 2020 16:15:09

**US3612060**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'SCRN'	System	30 Sep 2020 16:15:09

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered (b) (6) 1950'	(b) (4), (b) (6)	
	RWS_ENDPOINT	30 Sep 2020 14:03:00
	ENDPOINT (b) (4)	
	(b) (4)	

US3612060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:52:40
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
Query 'Source states 70, please review DOB and update source or EDC as needed. ' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:16:10
Comment added 'Corrected.'	Amy McMahan (b) (4)	21 Oct 2020 22:04:05
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:54:06
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:04
User opened query 'Source states 70, please review DOB and update source or EDC as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 17:53:59
User entered '69'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'YEARS'	System	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '69'	System	30 Sep 2020 16:17:29



**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered 'Male (M)'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:54:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:54:04
User entered 'I'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:54:04
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14



**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:09:47**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:54:04
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:17:14

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:03
User entered '30 Sep 2020'	Amy McMahan (b) (4)	30 Sep 2020 16:17:29

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Sep 2020'	System	30 Sep 2020 16:17:29

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2020'	System	30 Sep 2020 16:17:29

US3612060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:03
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:17:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:17:35
User entered 'Amendment 3 (3)' reason for change:	Amy McMahan (b) (4)	30 Sep 2020 16:17:35
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:17:29
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:17:29

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:03
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:17:29



**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:03
User entered empty.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:17:29

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:03
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:17:29

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:03
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:17:29

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:03
User entered 'US3612002'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	30 Sep 2020 14:02:59

**US3612060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:09:47**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'I'	System	30 Sep 2020 16:17:41

**US3612060**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:06
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:17:41

**US3612060**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:09:47**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:10
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:18:02

US3612060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:14
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:24:47
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 16:24:47
Data point term sent to Coder	System	30 Sep 2020 16:23:25
User entered 'HYPERTENSION'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:23:11



**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'UN UNK 2000'	Amy McMahan (b) (4)	30 Sep 2020 16:23:11

**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:23:11

**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:23:11

**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered empty.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:23:11

**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:23:11

**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2000'	System	30 Sep 2020 16:23:11

**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2000'	System	30 Sep 2020 16:23:11

**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	30 Sep 2020 16:23:11



**US3612060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	30 Sep 2020 16:23:11

US3612060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
User closed 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)	29 Oct 2020 05:17:19
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. ' answered with 'added' (Site from DM).	Kristin Pollock (b) (4)	28 Oct 2020 15:59:25
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)	27 Oct 2020 07:19:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Mitral valve repair, LLT: Mitral valve repair - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:25:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:25:50
Data point term sent to Coder	System	30 Sep 2020 16:24:27
User entered 'MITRAL VALVE REPAIR'	Amy McMahan (b) (4)	30 Sep 2020 16:23:52

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '28 May 2017'	Amy McMahan (b) (4)	30 Sep 2020 16:23:52

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:23:52
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:23:52

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered '28 May 2017'	Amy McMahan (b) (4)	30 Sep 2020 16:23:52
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	30 Sep 2020 16:23:52
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'May 2017'	System	30 Sep 2020 16:23:52



**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2017'	System	30 Sep 2020 16:23:52

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'May 2017'	System	30 Sep 2020 16:23:52

**US3612060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2017'	System	30 Sep 2020 16:23:52

US3612060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:25:51
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 16:25:51
Data point term sent to Coder	System	30 Sep 2020 16:24:27
User entered 'PROSTATECTOMY'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:24:27

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'UN UNK 2001'	Amy McMahan (b) (4)	30 Sep 2020 16:24:27

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:24:27
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:24:27

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered 'UN UNK 2001'	Amy McMahan (b) (4)	30 Sep 2020 16:24:27
	(b) (4)	



**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:24:27

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2001'	System	30 Sep 2020 16:24:27

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2001'	System	30 Sep 2020 16:24:27

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2001'	System	30 Sep 2020 16:24:27

**US3612060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2001'	System	30 Sep 2020 16:24:27

US3612060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:26:48
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 16:26:48
Data point term sent to Coder	System	30 Sep 2020 16:25:29
User entered 'PROSTATE CANCER'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:25:14

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered 'UN UNK 2001'	Amy McMahan (b) (4)	30 Sep 2020 16:25:14
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:25:14
	(b) (4)	



**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:25:14

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered 'UN UNK 2001'	Amy McMahan (b) (4)	30 Sep 2020 16:25:14
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	30 Sep 2020 16:25:14
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2001'	System	30 Sep 2020 16:25:14

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2001'	System	30 Sep 2020 16:25:14

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2001'	System	30 Sep 2020 16:25:14

**US3612060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2001'	System	30 Sep 2020 16:25:14

US3612060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
User closed 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)	29 Oct 2020 05:17:54
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. ' answered with 'added' (Site from DM).	Kristin Pollock (b) (4)	28 Oct 2020 15:59:37
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)	27 Oct 2020 07:20:03
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:14
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: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:27:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:27:47
Data point term sent to Coder	System	30 Sep 2020 16:26:31
User entered 'SPINAL FUSION'	Amy McMahan (b) (4)	30 Sep 2020 16:25:50



**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'UN UNK 2018'	Amy McMahan (b) (4)	30 Sep 2020 16:25:50

**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:25:50

**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:25:50
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered 'UN UNK 2018'	Amy McMahan (b) (4)	30 Sep 2020 16:25:50
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:25:50

**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2018'	System	30 Sep 2020 16:25:50

**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2018'	System	30 Sep 2020 16:25:50

**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2018'	System	30 Sep 2020 16:25:50



**US3612060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2018'	System	30 Sep 2020 16:25:50

US3612060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee total replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 12:46:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 12:46:42
Data point term sent to Coder	System	30 Sep 2020 16:27:36
User entered 'TOTAL KNEE REPLACEMENT, LEFT'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:26:49

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'UN UNK 1995'	Amy McMahan (b) (4)	30 Sep 2020 16:26:49

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:26:49
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:26:49

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered 'UN UNK 1995'	Amy McMahan (b) (4)	30 Sep 2020 16:26:49
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:26:49
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 1995'	System	30 Sep 2020 16:26:49



**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '1995'	System	30 Sep 2020 16:26:49

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 1995'	System	30 Sep 2020 16:26:49

**US3612060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '1995'	System	30 Sep 2020 16:26:49

US3612060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee total replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 12:55:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 12:55:59
Data point term sent to Coder	System	30 Sep 2020 16:27:37
User entered "TOTAL KNEE REPLACEMENT, RIGHT"	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'UN UNK 1998'	Amy McMahan (b) (4)	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:55:14
User entered 'UN UNK 1998'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:27:23



**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	21 Oct 2020 17:55:14
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 1998'	System	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '1998'	System	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 1998'	System	30 Sep 2020 16:27:23

**US3612060**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:09:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '1998'	System	30 Sep 2020 16:27:23

US3612060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:41:31
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:31:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:31:45
Data point term sent to Coder	System	28 Oct 2020 15:58:54
User entered 'Mitral Valve Regurgitation'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:58:23

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:41:33
User entered empty.	Kristin Pollock (b) (4)	28 Oct 2020 15:58:23
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:41:42
User entered 'l'	Kristin Pollock (b) (4)	28 Oct 2020 15:58:23
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:41:44
User entered 'No (N)'	Kristin Pollock (b) (4)	28 Oct 2020 15:58:23
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:41:47
User entered '28 May 2017'	Kristin Pollock (b) (4)	28 Oct 2020 15:58:23
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:41:49
User entered '0'	Kristin Pollock (b) (4)	28 Oct 2020 15:58:23

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	28 Oct 2020 15:58:23

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	28 Oct 2020 15:58:23

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'May 2017'	System	28 Oct 2020 15:58:23

**US3612060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2017'	System	28 Oct 2020 15:58:23

US3612060

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:40:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:33:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:33:41
Data point term sent to Coder	System	28 Oct 2020 15:59:56
User entered 'Degenerative Disc Disease'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:59:09



**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:40:29
User entered empty.	Kristin Pollock (b) (4)	28 Oct 2020 15:59:09
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:40:31
User entered 'l'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:59:09

**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:40:35
User entered 'No (N)'	Kristin Pollock (b) (4)	28 Oct 2020 15:59:09
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:42:10
Query 'Source states UNKNOWN. Please review and reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:42:09
User opened query 'Source states UNKNOWN. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:41:01
User entered 'un UNK 2018'	Kristin Pollock (b) (4)	28 Oct 2020 15:59:09
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:40:40
User entered '0'	Kristin Pollock (b) (4)	28 Oct 2020 15:59:09

**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	28 Oct 2020 15:59:09

**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	28 Oct 2020 15:59:09

**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jan 2018'	System	28 Oct 2020 15:59:09



**US3612060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2018'	System	28 Oct 2020 15:59:09

US3612060

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:40:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:11:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:11:20
Data point term sent to Coder	System	07 Dec 2020 17:46:27
User entered 'SEASONAL ALLERGIES'	Amy McMahan (b) (4) (b) (4)	07 Dec 2020 17:45:28

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:40:09
User entered empty.	Amy McMahan (b) (4)	07 Dec 2020 17:45:28

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:40:10
User entered 'I'	Amy McMahan (b) (4)	07 Dec 2020 17:45:28
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:40:12
User entered 'Yes (Y)'	Amy McMahan (b) (4)	07 Dec 2020 17:45:28
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	06 Apr 2021 19:40:14
User entered empty.	Amy McMahan (b) (4)	07 Dec 2020 17:45:28

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:40:16
User entered '0'	Amy McMahan (b) (4)	07 Dec 2020 17:45:28
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	07 Dec 2020 17:45:28



**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	07 Dec 2020 17:45:28

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	07 Dec 2020 17:45:28

**US3612060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	07 Dec 2020 17:45:28

US3612060

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:50:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:50:45
Data point term sent to Coder	System	13 Apr 2021 16:37:26
User entered 'Right shoulder pain'	Amber Stanford (b) (4)	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'un Jun 2016'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:36:41



**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jun 2016'	System	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2016'	System	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	13 Apr 2021 16:36:41

**US3612060**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	13 Apr 2021 16:36:41

US3612060

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:46:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Shoulder arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:03:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:03:56
Data point term sent to Coder	System	15 Apr 2021 19:02:51
User entered 'Right shoulder arthritis'	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:02:46

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:46:49
User entered 'un Jun 2016'	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:02:46

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User entered '0'	Amber Stanford (b) (4)	15 Apr 2021 19:02:46
	(b) (4)	



**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4)	15 Apr 2021 19:46:49
User entered 'Yes (Y)'	Amber Stanford (b) (4)	15 Apr 2021 19:02:46

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User entered empty.	Amber Stanford (b) (4)	15 Apr 2021 19:02:46
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 19:46:49
User entered '0'	Amber Stanford (b) (4)	15 Apr 2021 19:02:46
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'Jun 2016'	System	15 Apr 2021 19:02:46

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '2016'	System	15 Apr 2021 19:02:46

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	15 Apr 2021 19:02:46

**US3612060**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:09:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered empty.	System	15 Apr 2021 19:02:46

US3612060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:48
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:19:53



US3612060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:48
User entered '30 Sep 2020'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:48
User entered '09:24'	Amy McMahan (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '30 Sep 2020 09:24'	System	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:48
User entered '68.5' in	Amy McMahan (b) (4)	30 Sep 2020 16:19:53
DataPoint set to visible.	(b) (4)	30 Sep 2020 16:17:41

US3612060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:48
User entered '184' lb	Amy McMahan (b) (4)	30 Sep 2020 16:19:53
DataPoint set to visible.	(b) (4) System	30 Sep 2020 16:17:41

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered '27.62782'	System	30 Sep 2020 16:19:53
DataPoint set to visible.	System	30 Sep 2020 16:17:41

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'kg/m2'	System	30 Sep 2020 16:19:53
DataPoint set to visible.	System	30 Sep 2020 16:17:41

US3612060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:48
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:19:53



**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:48
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:48
User entered empty.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:48
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'bpm'	System	30 Sep 2020 16:19:53

US3612060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:48
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'breaths/min'	System	30 Sep 2020 16:19:53

US3612060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:48
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'mmHg'	System	30 Sep 2020 16:19:53



**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:48
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User entered 'mmHg'	System	30 Sep 2020 16:19:53

**US3612060**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48

US3612060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48

**US3612060**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:56:53
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:20:13
	(b) (4)	

**US3612060**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:53
User entered '30 Sep 2020'	Amy McMahan (b) (4)	30 Sep 2020 16:20:13

**US3612060**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:09:47**

**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51



US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

[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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

[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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:20:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:20:58
User entered 'No (N)' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:58
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:20:51
User entered empty.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

[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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

US3612060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:47

**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51



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Folder: Screening

Form: Risk of Exposure

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**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:09:47**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

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**Folder: Screening**

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

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Folder: Screening

Form: Risk of Exposure

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**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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered '0'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

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Folder: Screening

Form: Risk of Exposure

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[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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:56:57
User entered '0'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:20:51

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Folder: Screening

Form: Risk of Exposure

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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 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51



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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered 'l'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

**US3612060**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:09:47**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
User entered '0'	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

**US3612060**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:48
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:56:57
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:20:51

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:24
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:14:55

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:24
User entered '30 Sep 2020'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:14:55

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:24
User entered 'Clinic (Clinic)'	Amy McMahan (b) (4)	30 Sep 2020 16:14:55

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'VISIT1'	System	30 Sep 2020 16:14:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:47

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:42
User entered '30 SEP 2020'	(b) (4), (b) (6)	
	RWS_ENDPOINT	30 Sep 2020 14:53:29
	ENDPOINT (b) (4)	
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:42
User entered '191379'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	30 Sep 2020 14:53:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:42
User entered '>=65 years (3)'	(b) (4), (b) (6)	
	RWS_ENDPOINT	30 Sep 2020 14:53:29
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:47

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)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:42
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:14:46

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Folder: Visit 1 Day 1

Form: Randomization

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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)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:42
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:14:46

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:09:47**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:42
User entered 'No (N)'	Amy McMahan (b) (4)	30 Sep 2020 16:14:46

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:09:47**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:42
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:14:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:42
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:14:46

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:09:47**

**Human Immunodeficiency Virus (HIV) infection**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:42
User entered 'No (N)'	(b) (4), (b) (6)	
		21 Oct 2020 17:57:42
	Amy McMahan (b) (4)	30 Sep 2020 16:18:20
	(b) (4)	
DataPoint set to visible.	System	30 Sep 2020 16:17:35



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Pre-Dose (PREDOSE)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:22:00

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '30 Sep 2020'	Amy McMahan (b) (4)	30 Sep 2020 16:22:00

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '09:24'	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	30 Sep 2020 16:22:00
	(b) (4)	



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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '30 Sep 2020 09:24'	System	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '98.4' F	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	30 Sep 2020 16:22:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered 'Oral (Oral)'	Amy McMahan (b) (4)	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:22:00
	Amy McMahan (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '71'	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	30 Sep 2020 16:22:00
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'bpm'	System	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '16'	Amy McMahan (b) (4)	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'breaths/min'	System	30 Sep 2020 16:22:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered '133'	Amy McMahan (b) (4)	30 Sep 2020 16:22:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered '80'	Amy McMahan (b) (4)	30 Sep 2020 16:22:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:50
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Post-Dose (POSTDOSE)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 17:42:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 17:42:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:22:00
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:22:00



**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '30 Sep 2020' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '11:38' reason for change: Data Entry Error	(b) (4), (b) (6)	
		21 Oct 2020 17:57:50
User entered '11:38' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 20:28:49
	(b) (4)	
User entered '11:37' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
	(b) (4)	
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:22:00
	(b) (4)	

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '30 Sep 2020 11:38'	System	30 Sep 2020 20:28:49
User entered '30 Sep 2020 11:37'	System	30 Sep 2020 17:42:41
User entered empty.	System	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '98.2' F reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered 'Oral (Oral)' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:22:00

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered empty.	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	30 Sep 2020 16:22:00
	(b) (4)	

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '67' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User entered empty.	(b) (4)	30 Sep 2020 16:22:00

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'bpm'	System	30 Sep 2020 17:42:41
User entered empty.	System	30 Sep 2020 16:22:00



US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '16' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User entered empty.	(b) (4)	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'breaths/min'	System	30 Sep 2020 17:42:41
User entered empty.	System	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '137' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User entered empty.	(b) (4)	30 Sep 2020 16:22:00

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	30 Sep 2020 17:42:41
User entered empty.	System	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:57:50
User entered '89' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Sep 2020 17:42:41
User entered empty.	(b) (4)	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	30 Sep 2020 17:42:41
User entered empty.	System	30 Sep 2020 16:22:00

US3612060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:18
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:05

US3612060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:58:18
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:22:05



US3612060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:27
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:18:47

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:58:27
User entered empty.	Amy McMahan (b) (4)	30 Sep 2020 16:18:47

US3612060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

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)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:27
User entered empty.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:18:47

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 16:18:47

US3612060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:27
User entered '30 Sep 2020'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:18:47

US3612060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:27
User entered '11:05'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:18:47

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '30 Sep 2020 11:05'	System	30 Sep 2020 16:18:47

US3612060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:27
User entered 'Left Arm (LEFT ARM)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:18:47



**US3612060**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:58:27
User entered 'ONCE'	System	30 Sep 2020 16:18:47

US3612060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 16:18:47

US3612060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:34
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:20

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	21 Oct 2020 17:58:34
User entered '30 Sep 2020'	Amy McMahan (b) (4)	30 Sep 2020 16:22:20

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:34
User entered '09:55'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:20

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '30 Sep 2020 09:55'	System	30 Sep 2020 16:22:20

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:58:37
User entered '30 Sep 2020'	Amy McMahan (b) (4)	30 Sep 2020 16:22:31

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:31



**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:37
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:31

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:37
User entered '10:01'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:31

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '30 Sep 2020 10:01'	System	30 Sep 2020 16:22:31

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:31

US3612060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:37
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:31

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:58:37
User entered empty.	Amy McMahan (b) (4) (b) (4)	30 Sep 2020 16:22:31

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered empty.	System	30 Sep 2020 16:22:31

**US3612060**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:58:40
User entered 'Yes (Y)'	Amy McMahan (b) (4)	30 Sep 2020 16:22:36



**US3612060**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	30 Sep 2020 16:22:36

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:32:26', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '58280e27-190b-4bbb-9a73-0e6d8a50927a' User entered 'Yes (Y)'	System	30 Sep 2020 16:32:57
	System	30 Sep 2020 16:32:57

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:32:46', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '58280e27-190b-4bbb-9a73-0e6d8a50927a' User entered '98.2'	System	30 Sep 2020 16:32:57
	System	30 Sep 2020 16:32:57

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:32:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '58280e27-190b-4bbb-9a73-0e6d8a50927a' User entered 'No (N)'	System	30 Sep 2020 16:32:57
	System	30 Sep 2020 16:32:57

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:32:55', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '58280e27-190b-4bbb-9a73-0e6d8a50927a' User entered '30 Sep 2020 11:32'	System	30 Sep 2020 16:32:57
	System	30 Sep 2020 16:32:57

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 11:25'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 13:55'	System	30 Sep 2020 16:18:47



US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:09:35', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a858ebc0-e520-4d2c-87e9-86f806807f14' User entered 'Yes (Y)'	System	30 Sep 2020 23:10:02
	System	30 Sep 2020 23:10:02

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:09:46', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a858ebc0-e520-4d2c-87e9-86f806807f14' User entered '97.2'	System	30 Sep 2020 23:10:02
	System	30 Sep 2020 23:10:02

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:09:54', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a858ebc0-e520-4d2c-87e9-86f806807f14' User entered 'No (N)'	System	30 Sep 2020 23:10:02
	System	30 Sep 2020 23:10:02

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:09:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a858ebc0-e520-4d2c-87e9-86f806807f14' User entered '30 Sep 2020 18:09'	System	30 Sep 2020 23:10:02
	System	30 Sep 2020 23:10:02

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 14:50'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 2'	System	30 Sep 2020 16:18:47



US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:00:40', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c7d90642-42bb-4e9e-a859-57d65cca235f' User entered 'Yes (Y)'	System	01 Oct 2020 23:01:07
	System	01 Oct 2020 23:01:07

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:00:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c7d90642-42bb-4e9e-a859-57d65cca235f' User entered '97.5'	System	01 Oct 2020 23:01:07
	System	01 Oct 2020 23:01:07

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:00:55', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c7d90642-42bb-4e9e-a859-57d65cca235f' User entered 'No (N)'	System	01 Oct 2020 23:01:07
	System	01 Oct 2020 23:01:07

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:03', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c7d90642-42bb-4e9e-a859-57d65cca235f' User entered '01 Oct 2020 18:01'	System	01 Oct 2020 23:01:07
	System	01 Oct 2020 23:01:07

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 3'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:39:22', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '19b4c000-ee29-4fdc-81d2-d2e1bf48c36b' User entered 'Yes (Y)'	System	02 Oct 2020 19:39:44
	System	02 Oct 2020 19:39:44



US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:39:28', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '19b4c000-ee29-4fdc-81d2-d2e1bf48c36b' User entered '98.4'	System	02 Oct 2020 19:39:44
	System	02 Oct 2020 19:39:44

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:39:34', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '19b4c000-ee29-4fdc-81d2-d2e1bf48c36b' User entered 'No (N)'	System	02 Oct 2020 19:39:44
	System	02 Oct 2020 19:39:44

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:39:38', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '19b4c000-ee29-4fdc-81d2-d2e1bf48c36b' User entered '02 Oct 2020 14:39'	System	02 Oct 2020 19:39:44
	System	02 Oct 2020 19:39:44

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 4'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:02:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '812ffb6b-a726-4418-8f42-4553e52e8ade' User entered 'Yes (Y)'	System	04 Oct 2020 03:03:08
	System	04 Oct 2020 03:03:08

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:02:54', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '812ffb6b-a726-4418-8f42-4553e52e8ade' User entered '98.2'	System	04 Oct 2020 03:03:08
	System	04 Oct 2020 03:03:08



US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:02:58', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '812ffb6b-a726-4418-8f42-4553e52e8ade' User entered 'No (N)'	System	04 Oct 2020 03:03:08
	System	04 Oct 2020 03:03:08

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:02', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '812ffb6b-a726-4418-8f42-4553e52e8ade' User entered '03 Oct 2020 22:03'	System	04 Oct 2020 03:03:08
	System	04 Oct 2020 03:03:08

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 5'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:25:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '915a74c3-a258-4e3c-92bd-4d622c71b0ea' User entered 'Yes (Y)'	System	05 Oct 2020 00:25:57
	System	05 Oct 2020 00:25:57

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:25:46', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '915a74c3-a258-4e3c-92bd-4d622c71b0ea' User entered '96.7'	System	05 Oct 2020 00:25:57
	System	05 Oct 2020 00:25:57

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:25:50', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '915a74c3-a258-4e3c-92bd-4d622c71b0ea' User entered 'No (N)'	System	05 Oct 2020 00:25:57
	System	05 Oct 2020 00:25:57



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:25:53', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '915a74c3-a258-4e3c-92bd-4d622c71b0ea' User entered '04 Oct 2020 19:25'	System	05 Oct 2020 00:25:57
	System	05 Oct 2020 00:25:57

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 6'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:30:47', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a62443a9-168c-4864-9c29-ca5c91073e84' User entered 'Yes (Y)'	System	05 Oct 2020 22:31:01
	System	05 Oct 2020 22:31:01

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:30:53', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a62443a9-168c-4864-9c29-ca5c91073e84' User entered '98.1'	System	05 Oct 2020 22:31:01
	System	05 Oct 2020 22:31:01

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:30:55', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a62443a9-168c-4864-9c29-ca5c91073e84'	System	05 Oct 2020 22:31:01
User entered 'No (N)'	System	05 Oct 2020 22:31:01

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:30:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'a62443a9-168c-4864-9c29-ca5c91073e84' User entered '05 Oct 2020 17:30'	System	05 Oct 2020 22:31:01
	System	05 Oct 2020 22:31:01



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 7'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:46:50', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '919d86a4-c8c9-464d-b2a8-3e12abfdc60c' User entered 'Yes (Y)'	System	06 Oct 2020 22:47:09
	System	06 Oct 2020 22:47:09

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:46:56', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '919d86a4-c8c9-464d-b2a8-3e12abfdc60c' User entered '98.0'	System	06 Oct 2020 22:47:09
	System	06 Oct 2020 22:47:09

US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:46:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '919d86a4-c8c9-464d-b2a8-3e12abfdc60c' User entered 'No (N)'	System	06 Oct 2020 22:47:09
	System	06 Oct 2020 22:47:09

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:06', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '919d86a4-c8c9-464d-b2a8-3e12abfdc60c' User entered '06 Oct 2020 17:47'	System	06 Oct 2020 22:47:09
	System	06 Oct 2020 22:47:09

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



US3612060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:31:08', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '2cac803d-6fdf-4b8e-ae7b-2cc3f2af9662'	System	30 Sep 2020 16:31:38
User entered 'None (1)'	System	30 Sep 2020 16:31:38

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:31:13', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '2cac803d-6fdf-4b8e-ae7b-2cc3f2af9662' User entered 'No (N)'	System	30 Sep 2020 16:31:38
	System	30 Sep 2020 16:31:38

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:31:17', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '2cac803d-6fdf-4b8e-ae7b-2cc3f2af9662'	System	30 Sep 2020 16:31:38
User entered 'No (N)'	System	30 Sep 2020 16:31:38

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:31:26', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '2cac803d-6fdf-4b8e-ae7b-2cc3f2af9662'	System	30 Sep 2020 16:31:38
User entered 'None (1)'	System	30 Sep 2020 16:31:38

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:31:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '2cac803d-6fdf-4b8e-ae7b-2cc3f2af9662' User entered '30 Sep 2020 11:31'	System	30 Sep 2020 16:31:38
	System	30 Sep 2020 16:31:38

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 11:25'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 13:55'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:05:32', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e4893ae8-a63a-4eda-9d6c-86aa71b4b2ff' User entered 'None (1)'	System	30 Sep 2020 23:06:00
	System	30 Sep 2020 23:06:00

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:05:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e4893ae8-a63a-4eda-9d6c-86aa71b4b2ff' User entered 'No (N)'	System	30 Sep 2020 23:06:00
	System	30 Sep 2020 23:06:00

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:05:39', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e4893ae8-a63a-4eda-9d6c-86aa71b4b2ff' User entered 'No (N)'	System	30 Sep 2020 23:06:00
	System	30 Sep 2020 23:06:00

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:05:45', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e4893ae8-a63a-4eda-9d6c-86aa71b4b2ff' User entered 'None (1)'	System	30 Sep 2020 23:06:00
	System	30 Sep 2020 23:06:00

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:05:58', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e4893ae8-a63a-4eda-9d6c-86aa71b4b2ff' User entered '30 Sep 2020 18:05'	System	30 Sep 2020 23:06:00
	System	30 Sep 2020 23:06:00

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 14:50'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 2'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:11', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '459db95d-1000-41cb-ba16-78ccb970a3ca' User entered 'None (1)'	System	01 Oct 2020 23:01:39
	System	01 Oct 2020 23:01:39

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:15', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '459db95d-1000-41cb-ba16-78ccb970a3ca' User entered 'No (N)'	System	01 Oct 2020 23:01:39
	System	01 Oct 2020 23:01:39

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '459db95d-1000-41cb-ba16-78ccb970a3ca' User entered 'No (N)'	System	01 Oct 2020 23:01:39
	System	01 Oct 2020 23:01:39

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:29', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '459db95d-1000-41cb-ba16-78ccb970a3ca' User entered 'None (1)'	System	01 Oct 2020 23:01:39
	System	01 Oct 2020 23:01:39

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '459db95d-1000-41cb-ba16-78ccb970a3ca' User entered '01 Oct 2020 18:01'	System	01 Oct 2020 23:01:39
	System	01 Oct 2020 23:01:39

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 3'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:40:33', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b87e68e-740c-4939-be3d-6360969b3c6e' User entered 'None (1)'	System	02 Oct 2020 19:40:55
	System	02 Oct 2020 19:40:55

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:40:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b87e68e-740c-4939-be3d-6360969b3c6e' User entered 'No (N)'	System	02 Oct 2020 19:40:55
	System	02 Oct 2020 19:40:55

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:40:39', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b87e68e-740c-4939-be3d-6360969b3c6e' User entered 'No (N)'	System	02 Oct 2020 19:40:55
	System	02 Oct 2020 19:40:55

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:40:47', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b87e68e-740c-4939-be3d-6360969b3c6e' User entered 'None (1)'	System	02 Oct 2020 19:40:55
	System	02 Oct 2020 19:40:55

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:40:52', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b87e68e-740c-4939-be3d-6360969b3c6e' User entered '02 Oct 2020 14:40'	System	02 Oct 2020 19:40:55
	System	02 Oct 2020 19:40:55

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 4'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:09', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '68b80562-06ee-46cb-9360-3682a79d81ad' User entered 'None (1)'	System	04 Oct 2020 03:03:30
	System	04 Oct 2020 03:03:30

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:12', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '68b80562-06ee-46cb-9360-3682a79d81ad' User entered 'No (N)'	System	04 Oct 2020 03:03:30
	System	04 Oct 2020 03:03:30

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:15', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '68b80562-06ee-46cb-9360-3682a79d81ad' User entered 'No (N)'	System	04 Oct 2020 03:03:30
	System	04 Oct 2020 03:03:30

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:23', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '68b80562-06ee-46cb-9360-3682a79d81ad' User entered 'None (1)'	System	04 Oct 2020 03:03:30
	System	04 Oct 2020 03:03:30

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:27', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '68b80562-06ee-46cb-9360-3682a79d81ad' User entered '03 Oct 2020 22:03'	System	04 Oct 2020 03:03:30
	System	04 Oct 2020 03:03:30

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 5'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:05', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e20bb63d-47b0-456e-9487-6be3753977a2'	System	05 Oct 2020 00:26:22
User entered 'None (1)'	System	05 Oct 2020 00:26:22

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:08', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e20bb63d-47b0-456e-9487-6be3753977a2'	System	05 Oct 2020 00:26:22
User entered 'No (N)'	System	05 Oct 2020 00:26:22

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:11', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e20bb63d-47b0-456e-9487-6be3753977a2'	System	05 Oct 2020 00:26:22
User entered 'No (N)'	System	05 Oct 2020 00:26:22

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:15', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e20bb63d-47b0-456e-9487-6be3753977a2'	System	05 Oct 2020 00:26:22
User entered 'None (1)'	System	05 Oct 2020 00:26:22

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:18', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e20bb63d-47b0-456e-9487-6be3753977a2'	System	05 Oct 2020 00:26:22
User entered '04 Oct 2020 19:26'	System	05 Oct 2020 00:26:22

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 6'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:04', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'db1fee6f-eaaa-4891-abf8-7a8e70f24af3'	System	05 Oct 2020 22:31:23
User entered 'None (1)'	System	05 Oct 2020 22:31:23

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:07', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'db1fee6f-eaaa-4891-abf8-7a8e70f24af3'	System	05 Oct 2020 22:31:23
User entered 'No (N)'	System	05 Oct 2020 22:31:23

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:12', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'db1fee6f-eaaa-4891-abf8-7a8e70f24af3'	System	05 Oct 2020 22:31:23
User entered 'No (N)'	System	05 Oct 2020 22:31:23

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:15', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'db1fee6f-eaaa-4891-abf8-7a8e70f24af3'	System	05 Oct 2020 22:31:23
User entered 'None (1)'	System	05 Oct 2020 22:31:23

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'db1fee6f-eaaa-4891-abf8-7a8e70f24af3' User entered '05 Oct 2020 17:31'	System	05 Oct 2020 22:31:23
	System	05 Oct 2020 22:31:23

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 7'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:12', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f4649eee-eab1-4959-9fb9-a8fc5be91764' User entered 'None (1)'	System	06 Oct 2020 22:47:29
	System	06 Oct 2020 22:47:29

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:16', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f4649eee-eab1-4959-9fb9-a8fc5be91764' User entered 'No (N)'	System	06 Oct 2020 22:47:29
	System	06 Oct 2020 22:47:29

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:20', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f4649eee-eab1-4959-9fb9-a8fc5be91764' User entered 'No (N)'	System	06 Oct 2020 22:47:29
	System	06 Oct 2020 22:47:29

US3612060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:23', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f4649eee-eab1-4959-9fb9-a8fc5be91764' User entered 'None (1)'	System	06 Oct 2020 22:47:29
	System	06 Oct 2020 22:47:29

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:27', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f4649eee-eab1-4959-9fb9-a8fc5be91764' User entered '06 Oct 2020 17:47'	System	06 Oct 2020 22:47:29
	System	06 Oct 2020 22:47:29

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:13', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered 'None (0)'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:23', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered 'None (0)'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered 'None (0)'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered 'None (0)'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:45', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered 'None (0)'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered 'None (0)'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04



US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:54', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered 'No (N)'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T11:33:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1c518f3d-0293-42ec-ad07-d6c673b83666' User entered '30 Sep 2020 11:33'	System	30 Sep 2020 16:34:04
	System	30 Sep 2020 16:34:04

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 11:25'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 13:55'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:04', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered 'None (0)'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:08', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered 'None (0)'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:11', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered 'None (0)'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38



US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:14', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered 'None (0)'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:21', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered 'None (0)'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:25', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered 'None (0)'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:29', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered 'No (N)'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-09-30T18:06:34', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8935cb51-a640-443f-ac58-40ed22706cf9' User entered '30 Sep 2020 18:06'	System	30 Sep 2020 23:06:38
	System	30 Sep 2020 23:06:38

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Sep 2020 14:50'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 2'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:42', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered 'None (0)'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:44', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered 'None (0)'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered 'None (0)'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:01:52', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered 'None (0)'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:02:02', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered 'None (0)'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:02:05', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered 'None (0)'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:02:09', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered 'No (N)'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-01T18:02:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4e7e18e8-29b1-49d3-b8e4-d61062c2e98f' User entered '01 Oct 2020 18:02'	System	01 Oct 2020 23:02:21
	System	01 Oct 2020 23:02:21



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 3'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:40:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered 'None (0)'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:41:02', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered 'None (0)'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:41:06', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered 'None (0)'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:41:09', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered 'None (0)'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:41:13', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered 'None (0)'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:41:17', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered 'None (0)'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:41:21', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered 'No (N)'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-02T14:41:28', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9debcc11-cc75-474e-8bd5-a99dd9437f4a' User entered '02 Oct 2020 14:41'	System	02 Oct 2020 19:41:30
	System	02 Oct 2020 19:41:30

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 4'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:33', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered 'None (0)'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered 'None (0)'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:39', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered 'None (0)'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:43', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered 'None (0)'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:46', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered 'None (0)'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:49', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered 'None (0)'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:03:53', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered 'No (N)'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-03T22:04:01', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e79163d5-14fc-4dc9-950f-52ed43e0db52' User entered '03 Oct 2020 22:04'	System	04 Oct 2020 03:04:05
	System	04 Oct 2020 03:04:05

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 5'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:23', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered 'None (0)'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:27', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered 'None (0)'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:30', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered 'None (0)'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:32', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered 'None (0)'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:35', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered 'None (0)'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:37', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered 'None (0)'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered 'No (N)'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-04T19:26:45', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '40bcc19d-e4b2-4fb4-a191-4c6312d172e3' User entered '04 Oct 2020 19:26'	System	05 Oct 2020 00:26:49
	System	05 Oct 2020 00:26:49

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 6'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:24', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered 'None (0)'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:26', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered 'None (0)'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:30', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered 'None (0)'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:32', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered 'None (0)'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered 'None (0)'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:38', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered 'None (0)'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:43', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered 'No (N)'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-05T17:31:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e116a56f-23b6-4468-9ff4-db4bba1025a4' User entered '05 Oct 2020 17:31'	System	05 Oct 2020 22:31:55
	System	05 Oct 2020 22:31:55

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	30 Sep 2020 16:18:47
User entered 'Day 7'	System	30 Sep 2020 16:18:47

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:35', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered 'None (0)'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:37', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered 'None (0)'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:39', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered 'None (0)'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:42', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered 'None (0)'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:45', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered 'None (0)'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:47', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered 'None (0)'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01

US3612060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered 'No (N)'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-06T17:47:57', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e40e729f-94b7-484e-9483-42bf6a2f03de' User entered '06 Oct 2020 17:47'	System	06 Oct 2020 22:48:01
	System	06 Oct 2020 22:48:01

**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:18:47



**US3612060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:18:47

**US3612060**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:59:28
User entered 'Yes (Y)'	Amber Stanford (b) (4)	07 Oct 2020 19:16:09

**US3612060**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:59:28
User entered '07 Oct 2020'	Amber Stanford (b) (4)	07 Oct 2020 19:16:09
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:59:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	07 Oct 2020 19:16:09
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:59:28
User entered empty.	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 19:16:09

**US3612060**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:59:35
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 19:16:12

**US3612060**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	07 Oct 2020 19:16:12

**US3612060**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:59:44
User entered 'Yes (Y)'	Amber Stanford (b) (4)	14 Oct 2020 19:38:21



**US3612060**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	21 Oct 2020 17:59:44
User entered '14 Oct 2020'	Amber Stanford (b) (4)	14 Oct 2020 19:38:21

**US3612060**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:59:44
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	14 Oct 2020 19:38:21

**US3612060**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:59:44
User entered empty.	Amber Stanford (b) (4) (b) (4)	14 Oct 2020 19:38:21

**US3612060**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 17:59:48
User entered 'Yes (Y)'	Amber Stanford (b) (4)	14 Oct 2020 19:38:25
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	14 Oct 2020 19:38:25

**US3612060**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:57:06
User entered 'Yes (Y)'	Amber Stanford (b) (4)	21 Oct 2020 16:06:11
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	03 Nov 2020 20:57:06
User entered '21 Oct 2020'	Amber Stanford (b) (4)	21 Oct 2020 16:06:11

**US3612060**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	03 Nov 2020 20:57:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	21 Oct 2020 16:06:11
	(b) (4)	



US3612060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:57:06
User entered empty.	Amber Stanford (b) (4) (b) (4)	21 Oct 2020 16:06:11

US3612060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:57:15
User entered 'Yes (Y)'	Amber Stanford (b) (4)	21 Oct 2020 16:06:15
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	21 Oct 2020 16:06:15

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:19
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	28 Oct 2020 14:56:34

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:19
User entered '28 Oct 2020'	Kristin Pollock (b) (4)	28 Oct 2020 14:56:34

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:19
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4)	28 Oct 2020 14:56:34

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'VISIT2'	System	28 Oct 2020 14:56:34

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:27



US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered '28 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:27

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered '08:31'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '28 Oct 2020 08:31'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered '97.9' F	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered 'Oral (Oral)'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered empty.	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered '73'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	



**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'bpm'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered '16'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'breaths/min'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered '147'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered '81'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:27



US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:27

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered '28 Oct 2020'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered '10:10'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '28 Oct 2020 10:10'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered '97.6' F	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered 'Oral (Oral)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered empty.	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered '71'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:27



**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'bpm'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered '14'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'breaths/min'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:48:27
User entered '120'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:48:27
User entered '78'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:27
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	28 Oct 2020 15:47:27

US3612060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:49:45
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:40
	(b) (4)	



US3612060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:49:45
User entered '28 Oct 2020'	Kristin Pollock (b) (4)	28 Oct 2020 15:47:40

US3612060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:49:50
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 14:58:00

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:49:50
User entered empty.	Kristin Pollock (b) (4)	28 Oct 2020 14:58:00
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

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)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:49:50
User entered empty.	Kristin Pollock (b) (4)	28 Oct 2020 14:58:00

US3612060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'MRNA-1273 OR PLACEBO'	System	28 Oct 2020 14:58:00

US3612060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:49:50
User entered '28 Oct 2020'	Kristin Pollock (b) (4)	28 Oct 2020 14:58:00
	(b) (4)	

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:49:50
User entered '09:38'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 14:58:00

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '28 Oct 2020 09:38'	System	28 Oct 2020 14:58:00



US3612060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:49:50
User entered 'Left Arm (LEFT ARM)'	Kristin Pollock (b) (4)	28 Oct 2020 14:58:00
	(b) (4)	

US3612060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:49:50
User entered 'ONCE'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'INTRAMUSCULAR'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:49:56
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:54

US3612060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:49:56
User entered '28 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:54

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:49:56
User entered '08:40'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:47:54

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '28 Oct 2020 08:40'	System	28 Oct 2020 15:47:54

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:50:01
User entered '28 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:48:18



**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:48:18

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:50:01
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:48:18

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:50:01
User entered '08:48'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:48:18

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '28 Oct 2020 08:48'	System	28 Oct 2020 15:48:18

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:48:18

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:50:01
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:48:18

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:50:01
User entered empty.	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 15:48:18

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered empty.	System	28 Oct 2020 15:48:18



**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:50:05
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	28 Oct 2020 15:48:25

**US3612060**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	28 Oct 2020 15:48:25

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:10', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b79c174-d0eb-4831-ac3e-831be284feb3' User entered 'Yes (Y)'	System	28 Oct 2020 15:12:49
	System	28 Oct 2020 15:12:49

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:18', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b79c174-d0eb-4831-ac3e-831be284feb3' User entered '97.6'	System	28 Oct 2020 15:12:49
	System	28 Oct 2020 15:12:49

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:25', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b79c174-d0eb-4831-ac3e-831be284feb3' User entered 'No (N)'	System	28 Oct 2020 15:12:49
	System	28 Oct 2020 15:12:49

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:29', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9b79c174-d0eb-4831-ac3e-831be284feb3'	System	28 Oct 2020 15:12:49
User entered '28 Oct 2020 10:12'	System	28 Oct 2020 15:12:49

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 09:58'	System	28 Oct 2020 14:58:00



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 12:28'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:45:26', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aa2a6f10-592b-4899-944f-e0ef50eaa4ed' User entered 'Yes (Y)'	System	28 Oct 2020 20:45:45
	System	28 Oct 2020 20:45:45

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:45:32', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aa2a6f10-592b-4899-944f-e0ef50eaa4ed' User entered '97.8'	System	28 Oct 2020 20:45:45
	System	28 Oct 2020 20:45:45

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:45:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aa2a6f10-592b-4899-944f-e0ef50eaa4ed' User entered 'No (N)'	System	28 Oct 2020 20:45:45
	System	28 Oct 2020 20:45:45

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:45:43', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aa2a6f10-592b-4899-944f-e0ef50eaa4ed' User entered '28 Oct 2020 15:45'	System	28 Oct 2020 20:45:45
	System	28 Oct 2020 20:45:45

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 13:23'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 14:58:00



US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 2'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:01', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c9bdd5cc-e245-47a2-b2a1-a5c1675a5114' User entered 'Yes (Y)'	System	29 Oct 2020 23:03:17
	System	29 Oct 2020 23:03:17

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:07', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c9bdd5cc-e245-47a2-b2a1-a5c1675a5114' User entered '96.8'	System	29 Oct 2020 23:03:17
	System	29 Oct 2020 23:03:17

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:11', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c9bdd5cc-e245-47a2-b2a1-a5c1675a5114' User entered 'No (N)'	System	29 Oct 2020 23:03:17
	System	29 Oct 2020 23:03:17

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:15', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c9bdd5cc-e245-47a2-b2a1-a5c1675a5114' User entered '29 Oct 2020 18:03'	System	29 Oct 2020 23:03:17
	System	29 Oct 2020 23:03:17

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 3'	System	28 Oct 2020 14:58:00



US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 14:58:00



US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 4'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:52', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8dd36232-7036-4f0b-921e-1c6ac3877187' User entered 'Yes (Y)'	System	31 Oct 2020 21:03:10
	System	31 Oct 2020 21:03:10

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:58', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8dd36232-7036-4f0b-921e-1c6ac3877187' User entered '97.5'	System	31 Oct 2020 21:03:10
	System	31 Oct 2020 21:03:10

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:03:01', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8dd36232-7036-4f0b-921e-1c6ac3877187' User entered 'No (N)'	System	31 Oct 2020 21:03:10
	System	31 Oct 2020 21:03:10

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:03:05', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8dd36232-7036-4f0b-921e-1c6ac3877187' User entered '31 Oct 2020 16:03'	System	31 Oct 2020 21:03:10
	System	31 Oct 2020 21:03:10

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 5'	System	28 Oct 2020 14:58:00



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:13', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c3fb8693-82d2-4510-8025-cb88a62e6ee4' User entered 'Yes (Y)'	System	02 Nov 2020 00:50:29
	System	02 Nov 2020 00:50:29

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c3fb8693-82d2-4510-8025-cb88a62e6ee4' User entered '97.4'	System	02 Nov 2020 00:50:29
	System	02 Nov 2020 00:50:29

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:22', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c3fb8693-82d2-4510-8025-cb88a62e6ee4'	System	02 Nov 2020 00:50:29
User entered 'No (N)'	System	02 Nov 2020 00:50:29

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:26', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c3fb8693-82d2-4510-8025-cb88a62e6ee4' User entered '01 Nov 2020 18:50'	System	02 Nov 2020 00:50:29
	System	02 Nov 2020 00:50:29

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 6'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:48:33', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '94cb6c30-319d-46c7-bfb0-87cc719767c8' User entered 'Yes (Y)'	System	02 Nov 2020 20:48:55
	System	02 Nov 2020 20:48:55



US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:48:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '94cb6c30-319d-46c7-bfb0-87cc719767c8' User entered '98.3'	System	02 Nov 2020 20:48:55
	System	02 Nov 2020 20:48:55

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:48:44', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '94cb6c30-319d-46c7-bfb0-87cc719767c8'	System	02 Nov 2020 20:48:55
User entered 'No (N)'	System	02 Nov 2020 20:48:55

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:48:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '94cb6c30-319d-46c7-bfb0-87cc719767c8' User entered '02 Nov 2020 14:48'	System	02 Nov 2020 20:48:55
	System	02 Nov 2020 20:48:55

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 7'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:38:27', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e48ed92d-356f-4aa9-9544-7fda273af3ee' User entered 'Yes (Y)'	System	03 Nov 2020 21:38:46
	System	03 Nov 2020 21:38:46

US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:38:34', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e48ed92d-356f-4aa9-9544-7fda273af3ee' User entered '98.4'	System	03 Nov 2020 21:38:46
	System	03 Nov 2020 21:38:46



US3612060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:38:39', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e48ed92d-356f-4aa9-9544-7fda273af3ee' User entered 'No (N)'	System	03 Nov 2020 21:38:46
	System	03 Nov 2020 21:38:46

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:38:42', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e48ed92d-356f-4aa9-9544-7fda273af3ee' User entered '03 Nov 2020 15:38'	System	03 Nov 2020 21:38:46
	System	03 Nov 2020 21:38:46

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:38', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '705fa514-c7ec-4e60-b5a0-98f650cdc043'	System	28 Oct 2020 15:13:18
User entered 'None (1)'	System	28 Oct 2020 15:13:18

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '705fa514-c7ec-4e60-b5a0-98f650cdc043' User entered 'No (N)'	System	28 Oct 2020 15:13:18
	System	28 Oct 2020 15:13:18

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:44', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '705fa514-c7ec-4e60-b5a0-98f650cdc043' User entered 'No (N)'	System	28 Oct 2020 15:13:18
	System	28 Oct 2020 15:13:18



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '705fa514-c7ec-4e60-b5a0-98f650cdc043'	System	28 Oct 2020 15:13:18
User entered 'None (1)'	System	28 Oct 2020 15:13:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:53', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '705fa514-c7ec-4e60-b5a0-98f650cdc043' User entered '28 Oct 2020 10:12'	System	28 Oct 2020 15:13:18
	System	28 Oct 2020 15:13:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 09:58'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 12:28'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:46:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7bf7a2eb-e812-48c7-9246-bbb5b7054f39'	System	28 Oct 2020 20:47:01
User entered 'None (1)'	System	28 Oct 2020 20:47:01

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:46:45', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7bf7a2eb-e812-48c7-9246-bbb5b7054f39'	System	28 Oct 2020 20:47:01
User entered 'No (N)'	System	28 Oct 2020 20:47:01

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:46:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7bf7a2eb-e812-48c7-9246-bbb5b7054f39'	System	28 Oct 2020 20:47:01
User entered 'No (N)'	System	28 Oct 2020 20:47:01



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:46:52', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7bf7a2eb-e812-48c7-9246-bbb5b7054f39'	System	28 Oct 2020 20:47:01
User entered 'None (1)'	System	28 Oct 2020 20:47:01

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:46:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7bf7a2eb-e812-48c7-9246-bbb5b7054f39' User entered '28 Oct 2020 15:46'	System	28 Oct 2020 20:47:01
	System	28 Oct 2020 20:47:01

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 13:23'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 2'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:20', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '5ab08955-ead7-4c51-9f6a-a1678ad51ae3' User entered 'None (1)'	System	29 Oct 2020 23:03:41
	System	29 Oct 2020 23:03:41

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:23', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '5ab08955-ead7-4c51-9f6a-a1678ad51ae3' User entered 'No (N)'	System	29 Oct 2020 23:03:41
	System	29 Oct 2020 23:03:41

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:26', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '5ab08955-ead7-4c51-9f6a-a1678ad51ae3' User entered 'No (N)'	System	29 Oct 2020 23:03:41
	System	29 Oct 2020 23:03:41



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:29', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '5ab08955-ead7-4c51-9f6a-a1678ad51ae3' User entered 'None (1)'	System	29 Oct 2020 23:03:41
	System	29 Oct 2020 23:03:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:34', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '5ab08955-ead7-4c51-9f6a-a1678ad51ae3' User entered '29 Oct 2020 18:03'	System	29 Oct 2020 23:03:41
	System	29 Oct 2020 23:03:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 3'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:25', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'be0cdbaa-65ca-4fcc-a978-23ea6b4fab28'	System	30 Oct 2020 17:23:48
User entered 'None (1)'	System	30 Oct 2020 17:23:48

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:31', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'be0cdbaa-65ca-4fcc-a978-23ea6b4fab28' User entered 'No (N)'	System	30 Oct 2020 17:23:48
	System	30 Oct 2020 17:23:48

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:35', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'be0cdbaa-65ca-4fcc-a978-23ea6b4fab28' User entered 'No (N)'	System	30 Oct 2020 17:23:48
	System	30 Oct 2020 17:23:48



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:38', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'be0cdbaa-65ca-4fcc-a978-23ea6b4fab28' User entered 'None (1)'	System	30 Oct 2020 17:23:48
	System	30 Oct 2020 17:23:48

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:43', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'be0cdbaa-65ca-4fcc-a978-23ea6b4fab28' User entered '30 Oct 2020 12:23'	System	30 Oct 2020 17:23:48
	System	30 Oct 2020 17:23:48

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 4'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:01:50', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aefb359c-6ea3-415d-85bf-18ac85acb1f8'	System	31 Oct 2020 21:02:11
User entered 'None (1)'	System	31 Oct 2020 21:02:11

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:01:54', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aefb359c-6ea3-415d-85bf-18ac85acb1f8' User entered 'No (N)'	System	31 Oct 2020 21:02:11
	System	31 Oct 2020 21:02:11

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:01:57', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aefb359c-6ea3-415d-85bf-18ac85acb1f8' User entered 'No (N)'	System	31 Oct 2020 21:02:11
	System	31 Oct 2020 21:02:11



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aefb359c-6ea3-415d-85bf-18ac85acb1f8'	System	31 Oct 2020 21:02:11
User entered 'None (1)'	System	31 Oct 2020 21:02:11

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:06', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'aefb359c-6ea3-415d-85bf-18ac85acb1f8' User entered '31 Oct 2020 16:02'	System	31 Oct 2020 21:02:11
	System	31 Oct 2020 21:02:11

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 5'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:31', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '6e2616b7-57aa-4714-af34-04e840dd3fc7' User entered 'None (1)'	System	02 Nov 2020 00:51:00
	System	02 Nov 2020 00:51:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:35', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '6e2616b7-57aa-4714-af34-04e840dd3fc7' User entered 'No (N)'	System	02 Nov 2020 00:51:00
	System	02 Nov 2020 00:51:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:38', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '6e2616b7-57aa-4714-af34-04e840dd3fc7' User entered 'No (N)'	System	02 Nov 2020 00:51:00
	System	02 Nov 2020 00:51:00



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '6e2616b7-57aa-4714-af34-04e840dd3fc7' User entered 'None (1)'	System	02 Nov 2020 00:51:00
	System	02 Nov 2020 00:51:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:50:57', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '6e2616b7-57aa-4714-af34-04e840dd3fc7' User entered '01 Nov 2020 18:50'	System	02 Nov 2020 00:51:00
	System	02 Nov 2020 00:51:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 6'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:48:53', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8ae0a964-216b-4e5d-8434-656550d60858'	System	02 Nov 2020 20:49:09
User entered 'None (1)'	System	02 Nov 2020 20:49:09

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:48:56', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8ae0a964-216b-4e5d-8434-656550d60858' User entered 'No (N)'	System	02 Nov 2020 20:49:09
	System	02 Nov 2020 20:49:09

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:48:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8ae0a964-216b-4e5d-8434-656550d60858' User entered 'No (N)'	System	02 Nov 2020 20:49:09
	System	02 Nov 2020 20:49:09



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:01', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8ae0a964-216b-4e5d-8434-656550d60858'	System	02 Nov 2020 20:49:09
User entered 'None (1)'	System	02 Nov 2020 20:49:09

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:05', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '8ae0a964-216b-4e5d-8434-656550d60858' User entered '02 Nov 2020 14:49'	System	02 Nov 2020 20:49:09
	System	02 Nov 2020 20:49:09

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 7'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:38:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '65d3b9f7-5bc2-4e51-9a80-5985d9589632'	System	03 Nov 2020 21:39:11
User entered 'None (1)'	System	03 Nov 2020 21:39:11

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:38:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '65d3b9f7-5bc2-4e51-9a80-5985d9589632' User entered 'No (N)'	System	03 Nov 2020 21:39:11
	System	03 Nov 2020 21:39:11

US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:38:53', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '65d3b9f7-5bc2-4e51-9a80-5985d9589632' User entered 'No (N)'	System	03 Nov 2020 21:39:11
	System	03 Nov 2020 21:39:11



US3612060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:03', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '65d3b9f7-5bc2-4e51-9a80-5985d9589632'	System	03 Nov 2020 21:39:11
User entered 'None (1)'	System	03 Nov 2020 21:39:11

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:06', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '65d3b9f7-5bc2-4e51-9a80-5985d9589632' User entered '03 Nov 2020 15:39'	System	03 Nov 2020 21:39:11
	System	03 Nov 2020 21:39:11

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:12:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered 'None (0)'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:13:02', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered 'None (0)'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:13:04', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered 'None (0)'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:13:07', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered 'None (0)'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:13:09', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered 'None (0)'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:13:12', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered 'None (0)'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:13:16', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered 'No (N)'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T10:13:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '46512337-46a8-44bd-a1ff-0b421c92418e' User entered '28 Oct 2020 10:13'	System	28 Oct 2020 15:13:22
	System	28 Oct 2020 15:13:22

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 09:58'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 12:28'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 14:58:00



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:04', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered 'None (0)'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:07', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered 'None (0)'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:09', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered 'None (0)'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:12', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered 'None (0)'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:17', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered 'None (0)'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered 'None (0)'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:24', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered 'No (N)'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-28T15:47:29', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c2d5ce57-56c6-4dd6-be2c-2a3b4d52632e' User entered '28 Oct 2020 15:47'	System	28 Oct 2020 20:47:31
	System	28 Oct 2020 20:47:31



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '28 Oct 2020 13:23'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 2'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:38', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered 'None (0)'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:40', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered 'None (0)'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:43', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered 'None (0)'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:47', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered 'None (0)'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:49', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered 'None (0)'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered 'None (0)'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:56', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered 'No (N)'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-29T18:03:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '29e921de-80bf-4f1a-8a25-72ae5e8e6e49' User entered '29 Oct 2020 18:03'	System	29 Oct 2020 23:04:04
	System	29 Oct 2020 23:04:04

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 3'	System	28 Oct 2020 14:58:00

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:49', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered 'None (0)'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered 'None (0)'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:56', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered 'None (0)'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:23:59', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered 'None (0)'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:24:01', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered 'None (0)'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:24:03', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered 'None (0)'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:24:07', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered 'No (N)'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-30T12:24:15', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '356828df-624a-44bf-b741-260b644adce0' User entered '30 Oct 2020 12:24'	System	30 Oct 2020 17:24:18
	System	30 Oct 2020 17:24:18

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 14:58:00



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 4'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:13', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered 'None (0)'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:16', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered 'None (0)'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered 'None (0)'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:22', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered 'None (0)'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:24', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered 'None (0)'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:27', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered 'None (0)'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:30', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered 'No (N)'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-10-31T16:02:37', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '52557071-8743-4372-a9ed-cf8258ddd5ef' User entered '31 Oct 2020 16:02'	System	31 Oct 2020 21:02:41
	System	31 Oct 2020 21:02:41

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 5'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:04', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered 'None (0)'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:07', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered 'None (0)'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:08', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered 'None (0)'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:11', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered 'None (0)'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:13', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered 'None (0)'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:15', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered 'None (0)'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:18', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered 'No (N)'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-01T18:51:26', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd728890-1f6a-4808-8070-6585787f9de5' User entered '01 Nov 2020 18:51'	System	02 Nov 2020 00:51:30
	System	02 Nov 2020 00:51:30

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 6'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:12', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered 'None (0)'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:14', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered 'None (0)'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:16', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered 'None (0)'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered 'None (0)'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:21', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered 'None (0)'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:23', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered 'None (0)'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38

US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:27', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered 'No (N)'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-02T14:49:33', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cfefa073-17fd-420e-b7ca-99c148bb4bc9' User entered '02 Nov 2020 14:49'	System	02 Nov 2020 20:49:38
	System	02 Nov 2020 20:49:38

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 14:58:00



**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
Data entry locked.	System	28 Oct 2020 14:58:00
User entered 'Day 7'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:14', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered 'None (0)'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:16', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered 'None (0)'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:18', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered 'None (0)'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:20', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered 'None (0)'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:22', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered 'None (0)'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:24', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered 'None (0)'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40



US3612060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:47

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)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:27', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered 'No (N)'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-11-03T15:39:38', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '010f1ee8-bab4-4df6-9ed1-ee955df4158a' User entered '03 Nov 2020 15:39'	System	03 Nov 2020 21:39:40
	System	03 Nov 2020 21:39:40

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:09:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:36:19
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 14:58:00

**US3612060**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	18 Nov 2020 20:50:21
User entered 'Yes (Y)'	Amber Stanford (b) (4)	04 Nov 2020 17:10:08

**US3612060**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:50:21
User entered '04 Nov 2020'	Amber Stanford (b) (4)	04 Nov 2020 17:10:08
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	18 Nov 2020 20:50:21
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	04 Nov 2020 17:10:08

**US3612060**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:50:21
User entered empty.	Amber Stanford (b) (4) (b) (4)	04 Nov 2020 17:10:08



**US3612060**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:50:37
User entered 'Yes (Y)'	Amber Stanford (b) (4)	04 Nov 2020 17:10:12
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	04 Nov 2020 17:10:12

**US3612060**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	13 Nov 2020 15:43:13
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:40
User entered '13 Nov 2020'	Amber Stanford (b) (4)	13 Nov 2020 15:43:13

**US3612060**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	13 Nov 2020 15:43:13
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 20:36:40
User entered empty.	Amber Stanford (b) (4)	13 Nov 2020 15:43:13
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:45
User entered 'Yes (Y)'	Amber Stanford (b) (4)	13 Nov 2020 15:43:19

**US3612060**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	13 Nov 2020 15:43:19



**US3612060**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:24
User entered 'Yes (Y)'	Amber Stanford (b) (4)	19 Nov 2020 21:48:52

**US3612060**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:24
User entered '19 Nov 2020'	Amber Stanford (b) (4)	19 Nov 2020 21:48:52

**US3612060**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	19 Nov 2020 21:48:52
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:36:24
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Nov 2020 21:48:52

US3612060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	01 Dec 2020 20:36:32
User entered 'Yes (Y)'	Amber Stanford (b) (4)	19 Nov 2020 21:48:41

**US3612060**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	19 Nov 2020 21:48:41

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:20:57
User entered 'Yes (Y)'	Amy McMahan (b) (4)	01 Dec 2020 15:05:10

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:20:57
User entered '1 Dec 2020'	Amy McMahan (b) (4)	01 Dec 2020 15:05:10
	(b) (4)	



**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:20:57
User entered 'Clinic (Clinic)'	Amy McMahan (b) (4)	01 Dec 2020 15:05:10

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'VISIT3'	System	01 Dec 2020 15:05:10

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered 'Yes (Y)'	Amy McMahan (b) (4)	01 Dec 2020 15:04:44

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered '1 Dec 2020'	Amy McMahan (b) (4)	01 Dec 2020 15:04:44

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered '08:46'	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	01 Dec 2020 15:04:44
	(b) (4)	

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '1 Dec 2020 08:46'	System	01 Dec 2020 15:04:44

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered '97.6' F	Amy McMahan (b) (4)	01 Dec 2020 15:04:44

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered 'Oral (Oral)'	Amy McMahan (b) (4)	01 Dec 2020 15:04:44



**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered empty.	Amy McMahan (b) (4)	01 Dec 2020 15:04:44

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered '80'	Amy McMahan (b) (4)	01 Dec 2020 15:04:44

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'bpm'	System	01 Dec 2020 15:04:44

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered '16'	Amy McMahan (b) (4)	01 Dec 2020 15:04:44

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'breaths/min'	System	01 Dec 2020 15:04:44

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered '137'	Amy McMahan (b) (4)	01 Dec 2020 15:04:44

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	01 Dec 2020 15:04:44

US3612060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:04
User entered '84'	Amy McMahan (b) (4)	01 Dec 2020 15:04:44



**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'mmHg'	System	01 Dec 2020 15:04:44

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:19
User entered 'Yes (Y)'	Amy McMahan (b) (4)	01 Dec 2020 15:05:17

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:19
User entered '1 Dec 2020'	Amy McMahan (b) (4)	01 Dec 2020 15:05:17

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:21:51
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	01 Dec 2020 15:05:03

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:21:51
User entered '1 Dec 2020'	Amy McMahan (b) (4)	01 Dec 2020 15:05:03

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:21:51
User entered '08:48'	Amy McMahan (b) (4) (b) (4)	01 Dec 2020 15:05:03



**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered '1 Dec 2020 08:48'	System	01 Dec 2020 15:05:03

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:45
DataPoint Verified.	(b) (4)	22 Dec 2020 19:22:01
User entered 'Yes (Y)'	Amy McMahan (b) (4)	01 Dec 2020 15:05:21

**US3612060**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	01 Dec 2020 15:05:21

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-01T09:30:25', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cbf3c4c2-9f47-4390-9101-30ee9f312010' User entered 'No (N)'	System	01 Dec 2020 15:30:41
	System	01 Dec 2020 15:30:41

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-01T09:30:29', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cbf3c4c2-9f47-4390-9101-30ee9f312010'	System	01 Dec 2020 15:30:41
User entered 'No (N)'	System	01 Dec 2020 15:30:41

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-01T09:30:37', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cbf3c4c2-9f47-4390-9101-30ee9f312010' User entered '01 Dec 2020 09:30:37'	System	01 Dec 2020 15:30:41
	System	01 Dec 2020 15:30:41

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-04T08:03:21', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '25571e69-b243-4fcf-83bc-57176316fa64' User entered 'No (N)'	System	04 Dec 2020 14:03:31
	System	04 Dec 2020 14:03:31

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-04T08:03:25', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '25571e69-b243-4fcf-83bc-57176316fa64' User entered 'No (N)'	System	04 Dec 2020 14:03:31

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-04T08:03:29', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '25571e69-b243-4fcf-83bc-57176316fa64' User entered '04 Dec 2020 08:03:29'	System	04 Dec 2020 14:03:31
	System	04 Dec 2020 14:03:31

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-11T09:29:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd70635f-061f-433f-9b7a-f3a99bec1e9f' User entered 'No (N)'	System	11 Dec 2020 15:30:05
	System	11 Dec 2020 15:30:05

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-11T09:29:56', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd70635f-061f-433f-9b7a-f3a99bec1e9f' User entered 'No (N)'	System	11 Dec 2020 15:30:05
	System	11 Dec 2020 15:30:05

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-11T09:30:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'bd70635f-061f-433f-9b7a-f3a99bec1e9f' User entered '11 Dec 2020 09:30:00'	System	11 Dec 2020 15:30:05
	System	11 Dec 2020 15:30:05

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-18T17:57:17', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '3634075c-3a47-4a0b-b201-44198902e484' User entered 'No (N)'	System	18 Dec 2020 23:57:27

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-18T17:57:21', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '3634075c-3a47-4a0b-b201-44198902e484' User entered 'No (N)'	System	18 Dec 2020 23:57:27



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-18T17:57:24', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '3634075c-3a47-4a0b-b201-44198902e484' User entered '18 Dec 2020 17:57:24'	System	18 Dec 2020 23:57:27
	System	18 Dec 2020 23:57:27

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-25T10:48:45', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c9d2cba6-ad9b-4c10-8e72-3f2793cd3010' User entered 'No (N)'	System	25 Dec 2020 16:48:54
	System	25 Dec 2020 16:48:54

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-25T10:48:48', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c9d2cba6-ad9b-4c10-8e72-3f2793cd3010' User entered 'No (N)'	System	25 Dec 2020 16:48:54

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2020-12-25T10:48:51', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'c9d2cba6-ad9b-4c10-8e72-3f2793cd3010' User entered '25 Dec 2020 10:48:51'	System	25 Dec 2020 16:48:54
	System	25 Dec 2020 16:48:54

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-01T08:12:19', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f71bf359-23fb-44e5-9cd6-b02175f44111' User entered 'No (N)'	System	01 Jan 2021 14:12:35
	System	01 Jan 2021 14:12:35

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-01T08:12:25', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f71bf359-23fb-44e5-9cd6-b02175f44111'	System	01 Jan 2021 14:12:35
User entered 'No (N)'	System	01 Jan 2021 14:12:35

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-01T08:12:32', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f71bf359-23fb-44e5-9cd6-b02175f44111' User entered '01 Jan 2021 08:12:32'	System	01 Jan 2021 14:12:35
	System	01 Jan 2021 14:12:35

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-08T09:35:24', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '800bad7e-73c5-4800-bd23-04328f6a0703' User entered 'No (N)'	System	08 Jan 2021 15:35:36
	System	08 Jan 2021 15:35:36

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-08T09:35:30', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '800bad7e-73c5-4800-bd23-04328f6a0703' User entered 'No (N)'	System	08 Jan 2021 15:35:36
	System	08 Jan 2021 15:35:36

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-08T09:35:34', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '800bad7e-73c5-4800-bd23-04328f6a0703' User entered '08 Jan 2021 09:35:34'	System	08 Jan 2021 15:35:36
	System	08 Jan 2021 15:35:36

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-15T07:45:36', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '35e8f26c-4d61-4674-a674-dc5c805240e0' User entered 'No (N)'	System	15 Jan 2021 13:45:50
	System	15 Jan 2021 13:45:50

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-15T07:45:41', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '35e8f26c-4d61-4674-a674-dc5c805240e0' User entered 'No (N)'	System	15 Jan 2021 13:45:50
	System	15 Jan 2021 13:45:50



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-15T07:45:46', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '35e8f26c-4d61-4674-a674-dc5c805240e0' User entered '15 Jan 2021 07:45:46'	System	15 Jan 2021 13:45:50
	System	15 Jan 2021 13:45:50

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-22T15:58:12', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1e3b3402-6712-4cae-b82f-9ffb53f1296d' User entered 'No (N)'	System	22 Jan 2021 21:58:27

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-22T15:58:16', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1e3b3402-6712-4cae-b82f-9ffb53f1296d' User entered 'No (N)'	System	22 Jan 2021 21:58:27

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-22T15:58:25', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1e3b3402-6712-4cae-b82f-9ffb53f1296d' User entered '22 Jan 2021 15:58:25'	System	22 Jan 2021 21:58:27

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-29T08:55:52', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7820019f-c37e-49e2-825b-62dc306b912d' User entered 'No (N)'	System	29 Jan 2021 14:56:03
	System	29 Jan 2021 14:56:03

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-29T08:55:55', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7820019f-c37e-49e2-825b-62dc306b912d' User entered 'No (N)'	System	29 Jan 2021 14:56:03
	System	29 Jan 2021 14:56:03

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-01-29T08:56:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7820019f-c37e-49e2-825b-62dc306b912d' User entered '29 Jan 2021 08:56:00'	System	29 Jan 2021 14:56:03
	System	29 Jan 2021 14:56:03

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-05T08:17:53', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f82767f4-2283-425d-9d8d-3cc156328635' User entered 'No (N)'	System	05 Feb 2021 14:18:07
	System	05 Feb 2021 14:18:07

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-05T08:18:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f82767f4-2283-425d-9d8d-3cc156328635'	System	05 Feb 2021 14:18:07
User entered 'No (N)'	System	05 Feb 2021 14:18:07

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-05T08:18:03', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'f82767f4-2283-425d-9d8d-3cc156328635' User entered '05 Feb 2021 08:18:03'	System	05 Feb 2021 14:18:07
	System	05 Feb 2021 14:18:07

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-12T14:49:04', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1d0df312-6ca6-4693-ad93-41a2c4fc0174' User entered 'No (N)'	System	12 Feb 2021 20:49:13
	System	12 Feb 2021 20:49:13

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-12T14:49:06', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1d0df312-6ca6-4693-ad93-41a2c4fc0174' User entered 'No (N)'	System	12 Feb 2021 20:49:13
	System	12 Feb 2021 20:49:13



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-12T14:49:10', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '1d0df312-6ca6-4693-ad93-41a2c4fc0174' User entered '12 Feb 2021 14:49:10'	System	12 Feb 2021 20:49:13
	System	12 Feb 2021 20:49:13

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-19T08:13:57', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'b7b44953-879b-4fd3-b09d-772c76444407'	System	19 Feb 2021 14:14:11
User entered 'No (N)'	System	19 Feb 2021 14:14:11

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-19T08:14:03', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'b7b44953-879b-4fd3-b09d-772c76444407'	System	19 Feb 2021 14:14:11
User entered 'No (N)'	System	19 Feb 2021 14:14:11

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-19T08:14:09', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'b7b44953-879b-4fd3-b09d-772c76444407' User entered '19 Feb 2021 08:14:09'	System	19 Feb 2021 14:14:11
	System	19 Feb 2021 14:14:11

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-26T07:19:47-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4463113b-b324-474f-88b2-f0d3e3b4447b' User entered 'No (N)'	System	26 Feb 2021 13:20:05
	System	26 Feb 2021 13:20:05

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-26T07:19:50-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4463113b-b324-474f-88b2-f0d3e3b4447b' User entered 'No (N)'	System	26 Feb 2021 13:20:05
	System	26 Feb 2021 13:20:05

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-02-26T07:19:56-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '4463113b-b324-474f-88b2-f0d3e3b4447b' User entered '26 Feb 2021 13:19:56'	System	26 Feb 2021 13:20:05
	System	26 Feb 2021 13:20:05

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-05T13:15:35-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'd84d6528-fa99-471e-a121-f719edc497de'	System	05 Mar 2021 20:34:30
User entered 'No (N)'	System	05 Mar 2021 20:34:30

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-05T13:15:38-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'd84d6528-fa99-471e-a121-f719edc497de'	System	05 Mar 2021 20:34:30
User entered 'No (N)'	System	05 Mar 2021 20:34:30

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-05T13:15:41-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'd84d6528-fa99-471e-a121-f719edc497de' User entered '05 Mar 2021 13:15:41'	System	05 Mar 2021 20:34:30
	System	05 Mar 2021 20:34:30

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-12T07:53:31-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9e8ed477-67f4-4eb0-8077-f63283012cf6'	System	12 Mar 2021 13:53:51
User entered 'No (N)'	System	12 Mar 2021 13:53:51

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-12T07:53:40-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9e8ed477-67f4-4eb0-8077-f63283012cf6'	System	12 Mar 2021 13:53:51
User entered 'No (N)'	System	12 Mar 2021 13:53:51



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-12T07:53:44-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '9e8ed477-67f4-4eb0-8077-f63283012cf6' User entered '12 Mar 2021 07:53:44'	System	12 Mar 2021 13:53:51
	System	12 Mar 2021 13:53:51

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-19T15:17:49-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'dc267b16-6b16-4d71-b6b0-a00956339a6c'	System	19 Mar 2021 20:17:59
User entered 'No (N)'	System	19 Mar 2021 20:17:59

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-19T15:17:51-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'dc267b16-6b16-4d71-b6b0-a00956339a6c'	System	19 Mar 2021 20:17:59
User entered 'No (N)'	System	19 Mar 2021 20:17:59

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-19T15:17:57-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'dc267b16-6b16-4d71-b6b0-a00956339a6c' User entered '19 Mar 2021 15:17:57'	System	19 Mar 2021 20:17:59
	System	19 Mar 2021 20:17:59

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-26T08:05:02-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '66a79509-ec1a-4bbe-bd79-b0e74ad97206' User entered 'No (N)'	System	26 Mar 2021 13:05:14
	System	26 Mar 2021 13:05:14

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-26T08:05:06-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '66a79509-ec1a-4bbe-bd79-b0e74ad97206' User entered 'No (N)'	System	26 Mar 2021 13:05:14
	System	26 Mar 2021 13:05:14

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-26T08:05:10-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '66a79509-ec1a-4bbe-bd79-b0e74ad97206' User entered '26 Mar 2021 08:05:10'	System	26 Mar 2021 13:05:14
	System	26 Mar 2021 13:05:14

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-03T07:20:58-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7fba0ec3-0385-49c1-9360-20c605ad4aef'	System	03 Apr 2021 12:21:09
User entered 'No (N)'	System	03 Apr 2021 12:21:09

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-03T07:21:01-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7fba0ec3-0385-49c1-9360-20c605ad4aef' User entered 'No (N)'	System	03 Apr 2021 12:21:09

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-03T07:21:05-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '7fba0ec3-0385-49c1-9360-20c605ad4aef'	System	03 Apr 2021 12:21:09
User entered '03 Apr 2021 07:21:05'	System	03 Apr 2021 12:21:09

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-12T08:20:48-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e3d38d30-b6c5-4323-b496-08cfaeae55b2'	System	12 Apr 2021 13:21:00
User entered 'No (N)'	System	12 Apr 2021 13:21:00

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-12T08:20:53-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e3d38d30-b6c5-4323-b496-08cfaeae55b2'	System	12 Apr 2021 13:21:00
User entered 'No (N)'	System	12 Apr 2021 13:21:00



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-12T08:20:57-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'e3d38d30-b6c5-4323-b496-08cfaeae55b2'	System	12 Apr 2021 13:21:00
User entered '12 Apr 2021 08:20:57'	System	12 Apr 2021 13:21:00

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-16T15:59:01-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '146fa7dc-f8f0-4b51-8c34-b08753de3336'	System	16 Apr 2021 20:59:20
User entered 'No (N)'	System	16 Apr 2021 20:59:20

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-16T15:59:05-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '146fa7dc-f8f0-4b51-8c34-b08753de3336'	System	16 Apr 2021 20:59:20
User entered 'No (N)'	System	16 Apr 2021 20:59:20

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-16T15:59:10-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '146fa7dc-f8f0-4b51-8c34-b08753de3336'	System	16 Apr 2021 20:59:20
User entered '16 Apr 2021 15:59:10'	System	16 Apr 2021 20:59:20

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-23T12:23:20-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'dad08394-49e5-4a34-a637-4104caa0d720' User entered 'No (N)'	System	23 Apr 2021 17:23:34
	System	23 Apr 2021 17:23:34

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-23T12:23:25-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'dad08394-49e5-4a34-a637-4104caa0d720' User entered 'No (N)'	System	23 Apr 2021 17:23:34

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-23T12:23:28-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'dad08394-49e5-4a34-a637-4104caa0d720'	System	23 Apr 2021 17:23:34
User entered '23 Apr 2021 12:23:28'	System	23 Apr 2021 17:23:34

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-30T08:08:23-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cc011597-e02e-44ec-bdbd-c97c05d98585' User entered 'No (N)'	System	30 Apr 2021 13:08:35
	System	30 Apr 2021 13:08:35

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

Have you been exposed to someone with 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 (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-30T08:08:25-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cc011597-e02e-44ec-bdbd-c97c05d98585'	System	30 Apr 2021 13:08:35
User entered 'No (N)'	System	30 Apr 2021 13:08:35

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-04-30T08:08:30-05:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: 'cc011597-e02e-44ec-bdbd-c97c05d98585'	System	30 Apr 2021 13:08:35
User entered '30 Apr 2021 08:08:30'	System	30 Apr 2021 13:08:35

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 11:18:56



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 11:18:56

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**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 11:18:56

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 11:18:56



**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 11:18:56

**US3612060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:56
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 11:18:56

US3612060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:09:47

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:26:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-05T13:15:56-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '0c3e0ba7-ccb7-4dc4-a77e-8bcda91734e0'	System	05 Mar 2021 20:35:08
User entered 'No (N)'	System	05 Mar 2021 20:35:08

**US3612060**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:26:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CCF72D16-EDC2-4437-9333-591B202DF405)', Time: '2021-03-05T13:16:01-06:00', User OID: 'PatientReportedOutcome (US3612060)', ODM File OID: '0c3e0ba7-ccb7-4dc4-a77e-8bcda91734e0' User entered '05 Mar 2021 13:16:01'	System	05 Mar 2021 20:35:08
	System	05 Mar 2021 20:35:08



**US3612060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	06 Jan 2021 22:10:05
User entered 'Yes (Y)'	Amber Stanford (b) (4)	23 Dec 2020 17:43:18

**US3612060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	06 Jan 2021 22:10:05
User entered '23 Dec 2020'	Amber Stanford (b) (4)	23 Dec 2020 17:43:18

**US3612060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	06 Jan 2021 22:10:05
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	23 Dec 2020 17:43:18

**US3612060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:10:05
User entered empty.	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 17:43:18

**US3612060**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:06:35
DataPoint Verified.	(b) (4)	06 Jan 2021 22:10:00
User entered 'Yes (Y)'	Amber Stanford (b) (4)	23 Dec 2020 17:43:24

**US3612060**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:59:03
User entered 'I'	System	23 Dec 2020 17:43:24

**US3612060**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:41:31
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Feb 2021 15:31:52

**US3612060**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:41:31
User entered '25 Jan 2021'	Amy McMahan (b) (4)	17 Feb 2021 15:31:52



**US3612060**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:41:31
User entered 'Contact Made (CONTACT MADE)'	Amy McMahan (b) (4)	17 Feb 2021 15:31:52

**US3612060**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:41:31
User entered empty.	Amy McMahan (b) (4)	17 Feb 2021 15:31:52

**US3612060**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:43:02
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Feb 2021 15:31:29

**US3612060**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User entered 'I'	System	17 Feb 2021 15:31:29

**US3612060**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:43:27
User entered 'Yes (Y)'	Amber Stanford (b) (4)	25 Feb 2021 18:02:51

**US3612060**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:43:27
User entered '25 Feb 2021'	Amber Stanford (b) (4)	25 Feb 2021 18:02:51
	(b) (4)	

**US3612060**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:43:27
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	25 Feb 2021 18:02:51
	(b) (4)	

US3612060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:43:27
User entered empty.	Amber Stanford (b) (4)	25 Feb 2021 18:02:51



**US3612060**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:43:21
User entered 'Yes (Y)'	Amber Stanford (b) (4)	25 Feb 2021 18:02:55

**US3612060**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:44
User entered 'I'	System	25 Feb 2021 18:02:55

**US3612060**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:37:09
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
User entered 'Yes (Y)'	(b) (4) Amy McMahan (b) (4) (b) (4)	24 Mar 2021 16:32:19

**US3612060**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:37:09
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
User entered '24 Mar 2021'	(b) (4) Amy McMahan (b) (4) (b) (4)	24 Mar 2021 16:32:19

**US3612060**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:37:09
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy McMahan (b) (4) (b) (4)	24 Mar 2021 16:32:19

**US3612060**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:37:09
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
User entered empty.	(b) (4) Amy McMahan (b) (4) (b) (4)	24 Mar 2021 16:32:19

**US3612060**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:37:15
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
User entered 'Yes (Y)'	(b) (4) Amy McMahan (b) (4) (b) (4)	24 Mar 2021 16:32:24

**US3612060**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:47
User entered 'I'	System	24 Mar 2021 16:32:24



**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
	(b) (4)	
User entered 'Yes (Y)'	Amber Stanford (b) (4)	13 Apr 2021 14:51:58
	(b) (4)	

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
	(b) (4)	
User entered '13 Apr 2021'	Amber Stanford (b) (4)	13 Apr 2021 14:51:58
	(b) (4)	

US3612060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
	(b) (4)	
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	13 Apr 2021 14:51:58
	(b) (4)	

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 14:51:58

US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:52:04



US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:52:04

US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:52:04

US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04



**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:52:04

US3612060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:04

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:52:04

US3612060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:09

US3612060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:09

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:26

US3612060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '13 Apr 2021'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:26

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
	(b) (4)	
User entered '08:36'	Amber Stanford (b) (4)	13 Apr 2021 14:52:26
	(b) (4)	



**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:36'	System	13 Apr 2021 14:52:26

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	13 Apr 2021 14:52:32

**US3612060**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 14:52:32

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:20
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:00:08

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:20
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 18:00:08
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:20
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	06 Jan 2021 18:00:08

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 18:00:08

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:47

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:14
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 18:00:42
	(b) (4)	



**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:09:47**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:56:25
User entered '0'	Amber Stanford (b) (4)	08 Mar 2021 18:23:05
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 20:10:10

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:09:47**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:14
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:00:42

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:09:47**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:56:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	Amber Stanford (b) (4)	08 Mar 2021 18:23:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:10:10

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:14
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 18:00:42
	(b) (4)	

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:14
User entered 'Placebo (Placebo)'	Amber Stanford (b) (4)	06 Jan 2021 18:00:42
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:09:47**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:14
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:43:59
User entered 'Placebo (Placebo)'	Amber Stanford (b) (4)	06 Jan 2021 18:00:42
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:09:47**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:14
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:43:59
User entered 'Placebo (Placebo)'	Amber Stanford (b) (4)	06 Jan 2021 18:00:42
	(b) (4)	

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:14
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:00:42
	(b) (4)	



**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:09:47**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '1'	System	06 Jan 2021 18:00:42

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'I'	System	06 Jan 2021 18:00:42

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	06 Jan 2021 18:02:41
DataPoint set to visible.	System	06 Jan 2021 18:00:42

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	06 Jan 2021 18:02:41
DataPoint set to visible.	System	06 Jan 2021 18:00:42



US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Stanford (b) (4) (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered '11:09'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '06 Jan 2021 11:09'	System	06 Jan 2021 18:02:41

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '098.1' F	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered empty.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41



**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '071'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'bpm'	System	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '016'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'breaths/min'	System	06 Jan 2021 18:02:41

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '144'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '077'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	06 Jan 2021 18:02:41



US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:09:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	06 Jan 2021 18:02:41
DataPoint set to visible.	System	06 Jan 2021 18:00:42

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Stanford (b) (4) (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered '11:52'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '06 Jan 2021 11:52'	System	06 Jan 2021 18:02:41



US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '098.2' F	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered empty.	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '079'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'bpm'	System	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered '016'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'breaths/min'	System	06 Jan 2021 18:02:41

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:26
User entered '137'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41



**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:26
User entered '076'	Amber Stanford (b) (4)	06 Jan 2021 18:02:41
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	06 Jan 2021 18:02:41

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:09
User entered 'No (N)'	Amber Stanford (b) (4)	06 Jan 2021 18:03:22

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:09
User entered empty.	Amber Stanford (b) (4)	06 Jan 2021 18:03:22

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:01
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:03:50

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:01
User entered empty.	Amber Stanford (b) (4)	06 Jan 2021 18:03:50

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

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)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:01
User entered empty.	Amber Stanford (b) (4)	06 Jan 2021 18:03:50
	(b) (4)	



US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mRNA-1273'	System	06 Jan 2021 18:03:50
DataPoint set to visible.	System	06 Jan 2021 18:00:42

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:01
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 18:03:50

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:24:01
User entered '11:20'	Amber Stanford (b) (4)	06 Jan 2021 18:03:50

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '06 Jan 2021 11:20'	System	06 Jan 2021 18:03:50

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:24:01
User entered 'Left Arm (LEFT ARM)'	Amber Stanford (b) (4)	06 Jan 2021 18:03:50
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:24:01
User entered 'ONCE'	System	06 Jan 2021 18:03:50

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 18:03:50

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:23:32
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:04:31



US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:23:32
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 18:04:31

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:23:32
User entered '10:40'	Amber Stanford (b) (4)	06 Jan 2021 18:04:31

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '06 Jan 2021 10:40'	System	06 Jan 2021 18:04:31

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:23:23
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 17:59:58
	(b) (4)	

US3612060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:23:23
User entered '06 Jan 2021'	Amber Stanford (b) (4)	06 Jan 2021 17:59:58
	(b) (4)	

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:23:23
User entered '10:46'	Amber Stanford (b) (4)	06 Jan 2021 17:59:58

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:09:47**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '06 Jan 2021 10:46'	System	06 Jan 2021 17:59:58

**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	27 Jan 2021 16:23:27
User entered 'Yes (Y)'	Amber Stanford (b) (4)	06 Jan 2021 18:04:40



**US3612060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'I'	System	06 Jan 2021 18:04:40

**US3612060**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:44:11
User entered 'Yes (Y)'	Amber Stanford (b) (4)	14 Jan 2021 22:53:28

**US3612060**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:44:11
User entered '13 Jan 2021'	Amber Stanford (b) (4)	14 Jan 2021 22:53:28

**US3612060**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:44:11
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	14 Jan 2021 22:53:28

**US3612060**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:44:11
User entered empty.	Amber Stanford (b) (4)	14 Jan 2021 22:53:28

**US3612060**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:44:40
User entered 'Yes (Y)'	Amber Stanford (b) (4)	14 Jan 2021 22:53:32
	(b) (4)	

**US3612060**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User entered 'I'	System	14 Jan 2021 22:53:32

**US3612060**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User entered '1'	System	14 Jan 2021 22:53:32
DataPoint set to visible.	System	14 Jan 2021 22:53:32



**US3612060**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:44:51
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	02 Feb 2021 18:46:48

**US3612060**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:44:51
User entered '2 Feb 2021'	Kristin Pollock (b) (4)	02 Feb 2021 18:46:48

**US3612060**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:44:51
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4)	02 Feb 2021 18:46:48

**US3612060**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'OLD29'	System	02 Feb 2021 18:46:48

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '2 Feb 2021'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:04
User entered '11:05'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29



**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '2 Feb 2021 11:05'	System	02 Feb 2021 18:47:29

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:04
User entered '98.0' F	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered 'Oral (Oral)'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered empty.	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '73'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'bpm'	System	02 Feb 2021 18:47:29

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '16'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'breaths/min'	System	02 Feb 2021 18:47:29



**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '127'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	02 Feb 2021 18:47:29

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '75'	Kristin Pollock (b) (4)	02 Feb 2021 18:47:29
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	02 Feb 2021 18:47:29

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Pollock (b) (4) (b) (4)	02 Feb 2021 18:48:28

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:04
User entered '2 Feb 2021'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:04
User entered '11:59'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28



**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '2 Feb 2021 11:59'	System	02 Feb 2021 18:48:28

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '98.3' F	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered 'Oral (Oral)'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:04
User entered empty.	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:04
User entered '72'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'bpm'	System	02 Feb 2021 18:48:28

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:04
User entered '16'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'breaths/min'	System	02 Feb 2021 18:48:28



US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '130'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	02 Feb 2021 18:48:28

US3612060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:04
User entered '69'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:28
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mmHg'	System	02 Feb 2021 18:48:28

**US3612060**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:31
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:37
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:31
User entered '2 Feb 2021'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:37

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:40
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:55
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:40
User entered empty.	Kristin Pollock (b) (4)	02 Feb 2021 18:48:55



US3612060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:47

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)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:40
User entered empty.	Kristin Pollock (b) (4)	02 Feb 2021 18:48:55
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'mRNA-1273'	System	02 Feb 2021 18:48:55
DataPoint set to visible.	System	14 Jan 2021 22:53:32

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:40
User entered '2 Feb 2021'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:55
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:40
User entered '11:25'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:55
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '2 Feb 2021 11:25'	System	02 Feb 2021 18:48:55

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:45:40
User entered 'Left Arm (LEFT ARM)'	Kristin Pollock (b) (4)	02 Feb 2021 18:48:55
	(b) (4)	

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:45:40
User entered 'ONCE'	System	02 Feb 2021 18:48:55

**US3612060**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:09:47**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 18:48:55



**US3612060**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:45:49
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	02 Feb 2021 18:49:02

**US3612060**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'I'	System	02 Feb 2021 18:49:02

**US3612060**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:46:21
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Mar 2021 22:34:40

**US3612060**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:46:21
User entered '9 Feb 2021'	Kristin Pollock (b) (4)	04 Mar 2021 22:34:40

**US3612060**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:46:21
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4)	04 Mar 2021 22:34:40

**US3612060**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:06
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:46:21
User entered empty.	Kristin Pollock (b) (4)	04 Mar 2021 22:34:40

**US3612060**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:46:56
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Mar 2021 22:34:46

**US3612060**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:09:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'I'	System	04 Mar 2021 22:34:46



**US3612060**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:47:09
User entered 'Yes (Y)'	Amber Stanford (b) (4)	10 Mar 2021 22:13:46

**US3612060**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:47:09
User entered '10 Mar 2021'	Amber Stanford (b) (4)	10 Mar 2021 22:13:46
	(b) (4)	

**US3612060**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:47:09
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	10 Mar 2021 22:13:46
	(b) (4)	

**US3612060**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered 'OLD57'	System	10 Mar 2021 22:13:46

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:48:24
User entered 'No (N)'	Amber Stanford (b) (4)	10 Mar 2021 22:13:51
	(b) (4)	

US3612060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	10 Mar 2021 22:13:51



**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51
	(b) (4)	

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51
	(b) (4)	

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51
	(b) (4)	



**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:48:24
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:51
	(b) (4)	

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered empty.	System	10 Mar 2021 22:13:51

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00

**US3612060**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:47**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00

**US3612060**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:48:13
User entered 'No (N)'	Amber Stanford (b) (4)	10 Mar 2021 22:13:59
	(b) (4)	

**US3612060**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:09:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:48:13
User entered empty.	Amber Stanford (b) (4)	10 Mar 2021 22:13:59

**US3612060**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:47:16
User entered 'Yes (Y)'	Amber Stanford (b) (4)	10 Mar 2021 22:14:22
	(b) (4)	



**US3612060**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '10 Mar 2021'	Amber Stanford (b) (4)	10 Mar 2021 22:14:22
	(b) (4)	

**US3612060**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:47:16
User entered '14:17'	Amber Stanford (b) (4)	10 Mar 2021 22:14:22

**US3612060**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:45:00
User entered '10 Mar 2021 14:17'	System	10 Mar 2021 22:14:22

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**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:09:47**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:50:14
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4)	27 Jan 2021 16:25:01
User entered 'Yes (Y)'	Amber Stanford (b) (4)	20 Jan 2021 17:09:29

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:47

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User closed query 'Per MM: please confirm severity and seriousness assessment. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 17:48:37
Query 'Per MM: please confirm severity and seriousness assessment. ' answered with 'Subject required outpatient-day procedure but no hospitalization' (Site from DM).	Amber Stanford (b) (4) (b) (4)	28 Apr 2021 21:29:53
User opened query 'Per MM: please confirm severity and seriousness assessment. ' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 20:05:41
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:25:32
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:12:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:12:05
Data point term sent to Coder	System	20 Jan 2021 17:10:56
User entered 'Right Carpal Tunnel'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28



**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '29 Dec 2020'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User entered empty.	System	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '31 Dec 2020'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User entered empty.	System	20 Jan 2021 17:10:28



US3612060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:47

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:14:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 17:14:39
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:14:39
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:10:28
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 04:58:37
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Confirmed that AE was not serious ' (Site from System).	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:15:28
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).		20 Jan 2021 17:14:39
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:15:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 17:15:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:15:41
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:10:28
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28



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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:17:31
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Un-verified.	(b) (4)	
	Amber Stanford (b) (4)	07 Apr 2021 14:46:26
Signature has been broken.	(b) (4)	
	Amber Stanford (b) (4)	07 Apr 2021 14:46:26
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Amber Stanford (b) (4)	07 Apr 2021 14:46:26
User signature succeeded.	(b) (4)	
	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered '0'		
	Amber Stanford (b) (4)	20 Jan 2021 17:10:28
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'l'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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**Folder: Adverse Events**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:15:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:25:32
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 17:10:28

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User entered '0'	System	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48
User entered '1'	System	20 Jan 2021 17:10:28

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:03:48



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:20
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 19:47:44
User entered		
'USA-US129-2021-mRNA-1273-P301000005'	System	14 Apr 2021 18:50:55
User entered 'New'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	30 Apr 2021 20:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 16:42:45
	(b) (4), (b) (6)	26 Apr 2021 14:54:08
User closed query 'PV Query: Please consider updating event term to "worsening of rotator cuff arthritis" since it is part of medical history.' (Site from Safety).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder arthroplasty, LLT: Shoulder arthroplasty - version MedDRA\23.0.	Coder Import (b) (4)	25 Apr 2021 19:57:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Apr 2021 19:57:01
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder arthroplasty, LLT: Shoulder arthroplasty - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 16:55:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 16:55:02
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:53:47
DataPoint Un-verified.	Amy McMahan (b) (4)	23 Apr 2021 16:53:11
	(b) (4)	
User entered 'Total Shoulder Arthroplasty' reason for change: Data Entry Error	Amy McMahan (b) (4)	23 Apr 2021 16:53:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:50:12
	(b) (4)	
Query 'PV Query: Please consider updating event term to "worsening of rotator cuff arthritis" since it is part of medical history.' answered with 'updated' (Site from Safety).	Amy McMahan (b) (4)	23 Apr 2021 15:41:16
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:40:40
DataPoint Un-verified.	Amy McMahan (b) (4)	23 Apr 2021 15:40:10
	(b) (4)	
Coding entries removed.	Amy McMahan (b) (4)	23 Apr 2021 15:40:10
	(b) (4)	
Signature has been broken.	Amy McMahan (b) (4)	23 Apr 2021 15:40:10
	(b) (4)	
User entered 'WORSENING OF RIGHT ROTATOR CUFF ARTHRITIS' reason for change: Data Entry Error	Amy McMahan (b) (4)	23 Apr 2021 15:40:10
	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating event term to "worsening of rotator cuff arthritis" since it is part of medical history.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:29:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Shoulder arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 19:47:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 19:47:42
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	15 Apr 2021 21:34:36
User closed query 'Can you please update the SAE term to the underlying disease/condition which led to the procedure per CCG?' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:49:00
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:46
Data point term sent to Coder	System	15 Apr 2021 19:00:47
Query 'Can you please update the SAE term to the underlying disease/condition which led to the procedure per CCG?' answered with 'reconciled and updated' (Site from CRA).	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:00:36
Coding entries removed.	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:00:14
Signature has been broken.	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:00:14
User entered 'RIGHT ROTATOR CUFF Arthritis' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:00:14
User opened query 'Can you please update the SAE term to the underlying disease/condition which led to the procedure per CCG?' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 13:31:19
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	14 Apr 2021 14:51:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:21
Data point term sent to Coder	System	13 Apr 2021 16:48:40
User entered 'Right rotator Cuff repair'	Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:47:44

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EAB) (1725)

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**Folder: Adverse Events**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:04
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Yes (Y)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Form: Adverse Events (2)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:07
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:08
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '31 Mar 2021'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:47:44



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:12
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:23
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '02 Apr 2021'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:43
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:44
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Yes (Y)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:45
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44



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**Folder: Adverse Events**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:50
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:52
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'I'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:54
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '31 Mar 2021'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:42:59
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Completed.' (Site from Safety).	Amy McMahan (b) (4) (b) (4)	30 Apr 2021 19:02:36
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:45:03
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	14 Apr 2021 14:51:28
User entered '02 Apr 2021'	Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Amber Stanford (b) (4)	13 Apr 2021 16:47:44
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'I'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'I'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amber Stanford (b) (4)	13 Apr 2021 16:47:44



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:47:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	30 Apr 2021 20:56:40
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:54:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:50:32
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'updated. not aware of any covid-19 testing at this time. will follow up with subject. ' (Site from Safety).	Amy McMahan (b) (4) (b) (4)	23 Apr 2021 15:43:26
DataPoint Un-verified.	Amy McMahan (b) (4) (b) (4)	23 Apr 2021 15:42:46
Signature has been broken.	Amy McMahan (b) (4) (b) (4)	23 Apr 2021 15:42:46
User entered 'PATIENT REPORTS HAVING ELECTIVE RIGHT SHOULDER SURGERY FOR ROTATOR CUFF REPAIR D/T MEDICAL HISTORY OF RIGHT SHOULDER PAIN SECONDARY TO ARTHRITIS SINCE JUNE 2016. HE NOTES 2 NIGHT STAY IN THE HOSPITAL FOR POST-OPERATIVE RECOVERY W/O ANY COMPLICATIONS. PT DISCHARGED HOME ON ORAL TRAMADOL FOR PAIN. Site not aware of any COVID-19 testing done.' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	23 Apr 2021 15:42:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:28:45
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	15 Apr 2021 21:34:36
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:57
Signature has been broken.	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:00:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT REPORTS HAVING ELECTIVE RIGHT SHOULDER SURGERY FOR ROTATOR CUFF REPAIR D/T MEDICAL HISTORY OF RIGHT SHOULDER PAIN secondary to arthritis SINCE JUNE 2016. HE NOTES 2 NIGHT STAY IN THE HOSPITAL FOR POST-OPERATIVE RECOVERY W/O ANY COMPLICATIONS. PT DISCHARGED HOME ON ORAL TRAMADOL FOR PAIN.' reason for change: Data Entry Error User signature succeeded.	Amber Stanford (b) (4) (b) (4)	15 Apr 2021 19:00:14
	Richard Rupp (b) (4) (b) (4)	14 Apr 2021 14:51:28
User entered 'Patient reports having elective right shoulder surgery for rotator cuff repair d/t medical history of right shoulder pain since June 2016. He notes 2 night stay in the hospital for post-operative recovery w/o any complications. Pt discharged home on oral Tramadol for pain.'	Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:47:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:47:44

**US3612060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 16:47:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:09:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:50:14
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:48:49
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	30 Sep 2020 20:16:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
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)	24 Mar 2021 17:13:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 17:13:36
Data point term sent to Coder	System	24 Mar 2021 17:12:03
Coding entries removed.	Kristin Pollock (b) (4)	24 Mar 2021 17:11:43
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:22:47
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)	04 Dec 2020 19:40:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 19:40:04
Data point term sent to Coder	System	01 Dec 2020 18:11:39
Coding entries removed.	Amy McMahan (b) (4)	01 Dec 2020 18:11:19



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
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 20:18:43
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 20:18:43
Data point term sent to Coder	System	30 Sep 2020 20:17:49
User entered 'Aspirin'	Kristin Pollock (b) (4)	30 Sep 2020 20:17:02

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:43:42
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Un-verified.	Kristin Pollock (b) (4)	24 Mar 2021 17:11:43
User entered 'STROKE PREVENTION' reason for change: Data Entry Error	Kristin Pollock (b) (4)	24 Mar 2021 17:11:43
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Please update Con Med eCRF as appropriate.	(b) (4), (b) (6)	02 Dec 2020 14:48:46
' (Site from DM).		
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Please update Con Med eCRF as appropriate.	Amy McMahan (b) (4)	01 Dec 2020 18:11:26
' answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered 'STROKE PREVENTION' reason for change: Data Entry Error	Amy McMahan (b) (4)	01 Dec 2020 18:11:19
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Please update Con Med eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 13:16:46
' (Site from DM).		
User entered 'prophylaxis'	Kristin Pollock (b) (4)	30 Sep 2020 20:17:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '81'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'mg (mg)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'once daily (QD)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'un UNK 2017'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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**Folder: Concomitant Medication and Vaccination (1)**

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '0'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:02

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:17:02



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:17:02

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 20:17:02

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, COMBINATIONS, ATC: HMG COA REDUCTASE INHIBITORS, OTHER COMBINATIONS, PRODUCT: AMLODIPINE;ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 04:18:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 04:18:42
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 20:18:50
User entered 'Amlodipine/Atorvastatin'	Kristin Pollock (b) (4)	30 Sep 2020 20:17:50
	(b) (4)	

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Hypertension'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '5/20'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'mg (mg)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50



US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'once daily (QD)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'un UNK 2000'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '0'	Kristin Pollock (b) (4)	30 Sep 2020 20:17:50
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:17:50

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 20:17:50

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 20:19:45
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 20:19:45
Data point term sent to Coder	System	30 Sep 2020 20:18:51
User entered 'Acetaminophen'	Kristin Pollock (b) (4)	30 Sep 2020 20:18:46
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'knee and back pain'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '650'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46



US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'mg (mg)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'once daily (QD)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'un UNK 2018'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '0'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:18:46

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 20:18:46

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
User closed query 'FLUTICASONE' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:18:08
	(b) (4), (b) (6)	20 Jan 2021 21:18:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 22:18:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 22:18:58
Data point term sent to Coder	System	14 Jan 2021 22:17:27
Query 'FLUTICASONE' answered with 'UPDATED' (Site from CRA).	Amy McMahan (b) (4)	14 Jan 2021 22:17:08
DataPoint Un-verified.	Amy McMahan (b) (4)	14 Jan 2021 22:17:03
Coding entries removed.	Amy McMahan (b) (4)	14 Jan 2021 22:17:03
User entered 'FLUTICASONE' reason for change: Data Entry Error	Amy McMahan (b) (4)	14 Jan 2021 22:17:03
User opened query 'FLUTICASONE' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:28:29
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLUTICASON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 18:14:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 18:14:50
Data point term sent to Coder	System	01 Dec 2020 18:13:41
Coding entries removed.	Amy McMahan (b) (4)	01 Dec 2020 18:13:32

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US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLUTICASON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:22:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:22:47
Data point term sent to Coder	System	30 Sep 2020 20:19:53
User entered 'Fluticason'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User closed query 'Per CDM Re-Query: Please clarify the update made, as this indication has not been reported in Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:30:35
Query 'Per CDM Re-Query: Please clarify the update made, as this indication has not been reported in Medical History. Thank you' answered with 'UPDATED' (Site from DM).	Amy McMahan (b) (4)	07 Dec 2020 17:45:46
	(b) (4)	
User opened query 'Per CDM Re-Query: Please clarify the update made, as this indication has not been reported in Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:51:47
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	(b) (4), (b) (6)	02 Dec 2020 14:51:47
' (Site from DM).		
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	(b) (4), (b) (6)	02 Dec 2020 14:51:13
' (Site from DM).		
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	Amy McMahan (b) (4)	01 Dec 2020 18:13:42
	(b) (4)	
' answered with 'UPDATED' (Site from DM).		
Query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	Amy McMahan (b) (4)	01 Dec 2020 18:13:39
	(b) (4)	
' answered with 'UPDATED' (Site from DM).		

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

[Indication](#)

Audit	User	Time (GMT)
User entered 'SEASONAL ALLERGIES' reason for Amy McMahan change: Data Entry Error	(b) (4)	01 Dec 2020 18:13:32
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	(b) (4), (b) (6)	24 Nov 2020 14:06:39
' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 13:15:05
' (Site from DM).		
User entered 'allergies'	Kristin Pollock (b) (4)	30 Sep 2020 20:19:36
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '50'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'ug (ug)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 20:19:36
	(b) (4)	

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'as needed (PRN)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Nasal (NASAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'un UNK 2010'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '0'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:19:36



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:19:36

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:19:36

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: AZELASTINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 18:14:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 18:14:51
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 18:14:41
Coding entries removed.	Amy McMahan (b) (4)	01 Dec 2020 18:14:00
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: AZELASTINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 20:21:38
	(b) (4)	
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 20:21:38
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 20:20:54
User entered 'Azela	Kristin Pollock (b) (4)	30 Sep 2020 20:20:41
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User closed query 'Per CDM Re-Query: Please note that Seasonal Allergies has not been added to Medical History. Please review and update. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:30:59
Query 'Per CDM Re-Query: Please note that Seasonal Allergies has not been added to Medical History. Please review and update. Thank you' answered with 'UPDATED' (Site from DM).	Amy McMahan (b) (4)	07 Dec 2020 17:45:55
	(b) (4)	
User opened query 'Per CDM Re-Query: Please note that Seasonal Allergies has not been added to Medical History. Please review and update. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:56:35
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	(b) (4), (b) (6)	02 Dec 2020 14:56:35
' (Site from DM).		
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	Amy McMahan (b) (4)	01 Dec 2020 18:14:06
	(b) (4)	
' answered with 'UPDATED' (Site from DM).		
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Amy McMahan (b) (4)	01 Dec 2020 18:14:00
	(b) (4)	
Query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 14:07:51
' canceled (Site from DM).		

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:47

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:07:35
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 13:15:40
' (Site from DM).		
User entered 'allergies'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '137'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'ug (ug)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'as needed (PRN)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Nasal (NASAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'un UNK 2010'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '0'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:20:41

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:20:41

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 06:34:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 06:34:45
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 20:21:55
User entered 'Cialis'	Kristin Pollock (b) (4)	30 Sep 2020 20:21:31
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'prostatectomy'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '20'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'mg (mg)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'as needed (PRN)'	Kristin Pollock (b) (4)	30 Sep 2020 20:21:31
	(b) (4)	

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'un UNK 2001'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered '0'	Kristin Pollock (b) (4)	30 Sep 2020 20:21:31
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:21:31

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:21:31

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTS SYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:05:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:05:30
Data point term sent to Coder	System	30 Sep 2020 20:22:59
User entered 'Centrum Silver Adults 50 +'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44



US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:06:54
Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' answered with 'Prophylaxis updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	05 Nov 2020 17:52:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	05 Nov 2020 17:52:11
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 12:18:16
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'supplement'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'unk'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'tablet (TABLET)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'once daily (QD)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44



US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 20:22:44
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'I'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 20:22:52
User entered 'No (N)' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:22:44
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:22:44

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:22:44



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 20:22:44

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA 9 FATTY ACIDS;OMEGA-3 FATTY ACIDS;OMEGA-6 FATTY ACIDS, PRODUCTSYNONYM: OMEGA 3 6 9 [OMEGA 9 FATTY ACIDS;OMEGA-3 FATTY ACIDS;OMEGA-6 FATTY ACIDS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 20:24:35
User coded data point as Term Coded data point by	Coder Import (b) (4)	30 Sep 2020 20:24:35
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 20:24:01
User entered 'Omega 3-6-9'	Kristin Pollock (b) (4)	30 Sep 2020 20:23:42
	(b) (4)	

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:07:49
Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' answered with 'Prophylaxis updated' (Site from DM).	Amber Stanford (b) (4)	05 Nov 2020 17:54:17
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Amber Stanford (b) (4)	05 Nov 2020 17:54:13
	(b) (4)	
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 12:19:05
User entered 'No (N)'	Kristin Pollock (b) (4)	30 Sep 2020 20:23:42
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'supplement'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 20:49:43
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) (6)	21 Jan 2021 04:54:38
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).	Amber Stanford (b) (4)	19 Jan 2021 23:01:16
DataPoint Un-verified.	(b) (4)	
User entered '1000' reason for change: Data Entry Error	Amber Stanford (b) (4)	19 Jan 2021 23:01:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 12:04:54
User entered '780/420/150'	Kristin Pollock (b) (4)	30 Sep 2020 20:23:42
	(b) (4)	

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'mg (mg)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'once daily (QD)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'I'	Kristin Pollock (b) (4)	30 Sep 2020 20:23:42
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:23:42



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:23:42

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:23:42

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 20:23:42

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per source, patient took tylenoll for right hand pain from 29DEC2020 with no end date. Medication dose of 650mg PO once daily was not prophylactic nor a vaccine. No SAR. Please review and update EDC and/or source. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:37:52
Query 'Per source, patient took tylenoll for right hand pain from 29DEC2020 with no end date. Medication dose of 650mg PO once daily was not prophylactic nor a vaccine. No SAR. Please review and update EDC and/or source. ' answered with 'Reconciled and updated' (Site from CRA).	Amber Stanford (b) (4)	07 Apr 2021 14:45:27
User opened query 'Per source, patient took tylenoll for right hand pain from 29DEC2020 with no end date. Medication dose of 650mg PO once daily was not prophylactic nor a vaccine. No SAR. Please review and update EDC and/or source. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:45:31
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User coded data point as ATC: VARIOUS, ATC: ALLERGENS, ATC: ALLERGENS, ATC: ALLERGEN EXTRACTS, PRODUCT: ALLERGENS NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Dec 2020 18:16:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Dec 2020 18:16:49
Data point term sent to Coder	System	01 Dec 2020 18:15:42
Coding entries removed.	Amy McMahan (b) (4)	01 Dec 2020 18:14:52
User coded data point as ATC: VARIOUS, ATC: ALLERGENS, ATC: ALLERGENS, ATC: ALLERGEN EXTRACTS, PRODUCT: ALLERGENS NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 20:25:37
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 20:25:37
Data point term sent to Coder	System	30 Sep 2020 20:25:02

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EAB) (1725)

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US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Allergy Shots'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
User closed query 'source states yes' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:56
	(b) (4), (b) (6)	24 Mar 2021 20:48:46
Query 'source states yes' answered with 'updated to match source' (Site from CRA).	Kristin Pollock (b) (4)	24 Mar 2021 17:12:28
User entered 'Yes (Y)' reason for change: New Information	Kristin Pollock (b) (4)	24 Mar 2021 17:12:18
User opened query 'source states yes' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 20:50:23
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:32:57
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Kristin Pollock (b) (4)	26 Feb 2021 19:56:03
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kristin Pollock (b) (4)	26 Feb 2021 19:55:52
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4)	26 Feb 2021 19:55:52
	(b) (4), (b) (6)	25 Feb 2021 17:38:38
User closed query 'source states yes' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:31:27
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:30:27
Query 'source states yes' answered with 'reconciled and updated' (Site from CRA).	Amber Stanford (b) (4)	19 Jan 2021 23:01:55
DataPoint Un-verified.	(b) (4)	
	Amber Stanford (b) (4)	19 Jan 2021 23:01:44
	(b) (4)	

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	19 Jan 2021 23:01:44
User opened query 'source states yes' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:25:11
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User closed query 'Please note that Seasonal Allergies has not been updates in the Medical History CRF. Please review and update. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:31:33
Query 'Please note that Seasonal Allergies has not been updates in the Medical History CRF. Please review and update. Thank you' answered with 'UPDATED' (Site from DM).	Amy McMahan (b) (4)	07 Dec 2020 17:47:08
	(b) (4)	
User opened query 'Please note that Seasonal Allergies has not been updates in the Medical History CRF. Please review and update. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:59:07
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	(b) (4), (b) (6)	02 Dec 2020 14:59:07
' (Site from DM).		
Query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	Amy McMahan (b) (4)	01 Dec 2020 18:14:57
' answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Amy McMahan (b) (4)	01 Dec 2020 18:14:52
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the ALLERGIES. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 13:16:16
' (Site from DM).		
User entered 'allergies'	Kristin Pollock (b) (4)	30 Sep 2020 20:24:33
	(b) (4)	



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'unk'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Other (OTHER)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'unknown'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:42:51
DataPoint Un-verified.	Kristin Pollock (b) (4)	06 Apr 2021 17:02:03
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 17:02:03
	(b) (4)	
User entered 'every week (QS)' reason for change:	Kristin Pollock (b) (4)	06 Apr 2021 17:02:03
New Information	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'other (OTHER)'	Kristin Pollock (b) (4)	30 Sep 2020 20:24:33
	(b) (4)	

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
User closed query 'PER CDM: Response to frequency is weekly , kindly consider to update the response if applicable from the listed choices if any ( every week, twice daily, every month ...)Kindly update the response accordingly else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:01:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:42:53
Query 'PER CDM: Response to frequency is weekly , kindly consider to update the response if applicable from the listed choices if any ( every week, twice daily, every month ...)Kindly update the response accordingly else clarify.' answered with 'updated' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 17:02:21
DataPoint Un-verified.	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 17:02:03
Signature has been broken.	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 17:02:03
User entered empty; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 17:02:03
User opened query 'PER CDM: Response to frequency is weekly , kindly consider to update the response if applicable from the listed choices if any ( every week, twice daily, every month ...)Kindly update the response accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:50:00
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'weekly'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 20:24:33
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'I'	Kristin Pollock (b) (4)	30 Sep 2020 20:24:33
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:22:47
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 20:24:33

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:02:03
User entered empty.	System	30 Sep 2020 20:24:33

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:02:03
User entered empty.	System	30 Sep 2020 20:24:33

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	06 Apr 2021 17:02:03
User entered empty.	System	30 Sep 2020 20:24:33

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:38:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:50:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:50:40
Data point term sent to Coder	System	07 Apr 2021 14:49:38
User entered 'Tylenol'	Amber Stanford (b) (4) (b) (4)	07 Apr 2021 14:49:30



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:38:01
User entered 'No (N)'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:38:01
User entered 'Right hand pain/Carpal Tunnel'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered '650'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:38:01
User entered 'mg (mg)'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered empty.	Amber Stanford (b) (4)	07 Apr 2021 14:49:30

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Apr 2021 15:38:01
	(b) (4)	
	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered empty.	Amber Stanford (b) (4)	07 Apr 2021 14:49:30

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:38:01
User entered 'Oral (ORAL)'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered empty.	Amber Stanford (b) (4)	07 Apr 2021 14:49:30

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered '29 Dec 2020'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:38:01
User entered '0'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:38:01
User entered 'No (N)'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered '12 Jan 2021'	Amber Stanford (b) (4)	07 Apr 2021 14:49:30

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:12
DataPoint Verified.	(b) (4)	08 Apr 2021 15:38:01
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 15:38:01
	(b) (4)	
	Amber Stanford (b) (4)	07 Apr 2021 14:49:30
	(b) (4)	

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User entered '1'	System	07 Apr 2021 14:49:30

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User entered '1'	System	07 Apr 2021 14:49:30



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:27:04
User entered '804 (804)'	System	07 Apr 2021 14:49:30

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 08:27:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:27:49
Data point term sent to Coder	System	13 Apr 2021 16:54:47
User entered 'Tramadol'	Amber Stanford (b) (4) (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Right shoulder pain post-operative rotator cuff repair'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '50'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'mg (mg)'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'twice daily (BID)'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37



US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	(b) (4) Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Oral (ORAL)'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

US3612060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '02 Apr 2021'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '0'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Yes (Y)'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:50:29
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'No (N)'	Amber Stanford (b) (4)	13 Apr 2021 16:54:37



**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:54:37

**US3612060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:09:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:54:37

US3612060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:09:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:50:14
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy McMahan (b) (4)	04 Feb 2021 20:13:07
User entered 'No (N)'	(b) (4)	04 Feb 2021 16:38:03
	Amy McMahan (b) (4)	
	(b) (4)	

**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:09:47**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:32
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:45
User entered '31 Dec 2020'	Amy McMahan (b) (4)	04 Feb 2021 20:17:38

US3612060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:32
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:45
User entered 'Right Carpal Tunnel Surgery'	Amy McMahan (b) (4)	04 Feb 2021 20:17:38

US3612060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:32
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 20:51:45
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:24:58
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated MH' (Site from DM).	Kristin Pollock (b) (4)	26 Feb 2021 20:06:46
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:34:20
User entered 'Medical History (MH)'	Amy McMahan (b) (4)	04 Feb 2021 20:17:38

**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:09:47**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:32
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:45
User entered empty.	Amy McMahan (b) (4)	04 Feb 2021 20:17:38



**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:09:47**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:45
User entered '29 Dec 2020'	Kristin Pollock (b) (4)	26 Feb 2021 20:07:26

**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:45
User entered 'EMG (electromyographic nerve study)'	Kristin Pollock (b) (4)	26 Feb 2021 20:07:26

**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:45
User entered 'Diagnostic (DIAGNOSTIC)'	Kristin Pollock (b) (4)	26 Feb 2021 20:07:26

US3612060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:06:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:20:04
DataPoint Verified.	(b) (4)	23 Mar 2021 20:51:45
User entered empty.	Kristin Pollock (b) (4)	26 Feb 2021 20:07:26
	(b) (4)	

**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:09:47**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:50
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered '31 Mar 2021'	Amber Stanford (b) (4)	13 Apr 2021 16:43:15

**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:50
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Right Rotator Cuff Repair'	Amber Stanford (b) (4)	13 Apr 2021 16:43:15

**US3612060**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:50
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered 'Medical History (MH)'	Amber Stanford (b) (4)	13 Apr 2021 16:43:15

US3612060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:47

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:50
User signature succeeded.	Richard Rupp (b) (4)	14 Apr 2021 14:51:28
User entered empty.	Amber Stanford (b) (4)	13 Apr 2021 16:43:15



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:29:59
User entered		
'USA-US129-2021-MRNA-1273-P301000005'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Richard'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Rupp'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered '301 University Blvd'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Galveston'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'TX'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered '77555'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'US'	(b) (4), (b) (6)	14 Apr 2021 18:51:27

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:54:40
User entered '2'	System	15 Apr 2021 20:22:51
User entered '1'	System	14 Apr 2021 18:51:27



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:29:59
User entered		
'USA-US129-2021-MRNA-1273-P301000005'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Richard'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Rupp'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered '301 University Blvd'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Galveston'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'TX'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered '77555'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'US'	(b) (4), (b) (6)	14 Apr 2021 18:51:27

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:54:40
User entered '2'	System	15 Apr 2021 20:22:51
User entered '1'	System	14 Apr 2021 18:51:27



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:09:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered '14/Apr/2021 14:51'	System	14 Apr 2021 18:51:27

US3612060

Folder: SAE USA-US129-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:09:47

**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)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 18:51:27

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:29:59
User entered		
'USA-US129-2021-MRNA-1273-P301000005'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Richard'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Rupp'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered '301 University Blvd'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Galveston'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'TX'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered '77555'	System	14 Apr 2021 18:50:55



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'US'	System	14 Apr 2021 18:51:27

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:54:40
User entered '2'	System	15 Apr 2021 20:22:51
User entered '1'	System	14 Apr 2021 18:51:27

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:09:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:06
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
User entered '15/Apr/2021 13:22'	(b) (4) System	15 Apr 2021 20:22:51

US3612060

Folder: SAE USA-US129-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:09:47

**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)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:08
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 21:34:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:22:51

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:29:59
User entered		
'USA-US129-2021-MRNA-1273-P301000005'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'No (N)'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Richard'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'Rupp'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered '301 University Blvd'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'Galveston'	(b) (4), (b) (6)	14 Apr 2021 18:50:55



**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 13:30:01
User entered 'TX'	System	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered '77555'	(b) (4), (b) (6)	14 Apr 2021 18:50:55

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:54:28
User signature succeeded.	Richard Rupp (b) (4)	15 Apr 2021 15:11:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:30:01
User entered 'US'	(b) (4), (b) (6)	14 Apr 2021 18:51:27

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:54:40
User entered '2'	System	15 Apr 2021 20:22:51
User entered '1'	System	14 Apr 2021 18:51:27

**US3612060**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:09:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 15:28:53
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:22
User entered '26/Apr/2021 10:54'	(b) (4) System	26 Apr 2021 14:54:40

US3612060

Folder: SAE USA-US129-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:09:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 15:28:54
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:22
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 14:54:40