

US3112365 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:13:11

All time stamps listed in this document are displayed in GMT

US3112365

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

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Participant ID

US3112365

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

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US3112365

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:12:38

Generated On: 09 Jun 2021 15:13:11

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

US3112365

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Date of Birth (MMM yyyy)	(b) (6) 1951
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) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3112365

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

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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) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3112365

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3112365

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Condition	OSTEOARTHRITIS-BILATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

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



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:12:38

Generated On: 09 Jun 2021 15:13:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:55
Height (xxx.x)	70 in
Weight (xxx.x)	236 lb
BMI (xxx.x)	33.93328 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:12:30

Generated On: 09 Jun 2021 15:13:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3112365

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:12:38

Generated On: 09 Jun 2021 15:13:11

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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) 19 Feb 2021 17:12:38

Generated On: 09 Jun 2021 15:13:11

<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) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 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) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

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

What was the participant's randomization number? 187689

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) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Height	ND - Not Done
Weight	ND - Not Done

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:55
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

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)	24 AUG 2020
Time of assessment (00:00-23:59)	16:59 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:59
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

24 AUG 2020

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*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) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 16:28 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 16:28

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) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 AUG 2020
Collection time (00:00-23:59)	15:03 (24 HR)
Collection date and time (derived)	24 AUG 2020 15:03

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:57	24 AUG 2020 13:57
Nasopharyngeal Swab 2	No		

US3112365

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 17:00

PC Open Date & Time

24 AUG 2020 16:48

PC Close Date & Time

24 AUG 2020 19:18

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 AUG 2020 20:13

PC Close Date & Time

25 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

25 AUG 2020 14:28

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:54

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 14:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**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

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

28 AUG 2020 13:12

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**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

98.5 °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

29 AUG 2020 15:52

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**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

98.5 °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

30 AUG 2020 15:16

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 17:01

PC Open Date & Time

24 AUG 2020 16:48

PC Close Date & Time

24 AUG 2020 19:18

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 AUG 2020 20:13

PC Close Date & Time

25 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 14:29

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:54

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 14:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 13:11

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 15:53

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 15:16

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**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 ☐

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 17:01
PC Open Date & Time	24 AUG 2020 16:48
PC Close Date & Time	24 AUG 2020 19:18

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**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 ☐

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 AUG 2020 20:13

PC Close Date & Time

25 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**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 ☒

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 14:29
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**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: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:54
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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 ☒

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EAB) (1725)

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 14:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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 ☒

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 13:12
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 15:53
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 15:16
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3112365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

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

Visit date (dd MMM yyyy)	21 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	VISIT2
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US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:25
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	079 mmHg
Diastolic Blood Pressure units	MMHG



US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:45
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	088 mmHg
Diastolic Blood Pressure units	MMHG

US3112365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 11:14 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 11:14

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

US3112365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

10:50 (24 HR)

Collection date and time (derived)

21 SEP 2020 10:50

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	21 SEP 2020 10:40
Nasopharyngeal Swab 2	No		

US3112365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**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

98.7 °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

21 SEP 2020 11:44

PC Open Date & Time

21 SEP 2020 11:34

PC Close Date & Time

21 SEP 2020 14:04

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 21 SEP 2020 14:59

PC Close Date & Time 22 SEP 2020 11:59



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 17:57

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**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

98.1 °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

23 SEP 2020 15:19

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 14:05

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**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

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

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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**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

98.1 °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

27 SEP 2020 13:21

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

---

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

21 SEP 2020 11:45

PC Open Date & Time

21 SEP 2020 11:34

PC Close Date & Time

21 SEP 2020 14:04

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 14:59

PC Close Date & Time

22 SEP 2020 11:59



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**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

22 SEP 2020 17:58

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**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

23 SEP 2020 15:19

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**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

24 SEP 2020 18:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**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

25 SEP 2020 14:05

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**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

27 SEP 2020 13:21

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**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 ☐

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 11:46
PC Open Date & Time	21 SEP 2020 11:34
PC Close Date & Time	21 SEP 2020 14:04



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**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 ☐

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 14:59

PC Close Date & Time

22 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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 ☒

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 17:58
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2475

EAB) (1725)

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 15:20
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

102 of 2475

EAB) (1725)

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:45
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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 ☒

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 14:06
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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 ☒

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 13:22
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 28 SEP 2020 16:15

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

28 SEP 2020 16:15

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3112365

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 28 SEP 2020 16:15

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3112365

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:13:11

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 16:15
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3112365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:56:39

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

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

US3112365

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:08

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	VISIT3

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 10:15
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

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.*

US3112365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

19 OCT 2020 10:25

US3112365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:09

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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

22 NOV 2020 15:47:14

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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 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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2020 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2020 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2020 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2020 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2020 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 14:30:31
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 17:22:55
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 09:01:40

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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24 JAN 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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

29 JAN 2021 19:31:16

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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

04 FEB 2021 11:15:40

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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

17 FEB 2021 10:48:25

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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24 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 08:58:48
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 09:08:39
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 12:17:09

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 16:03:45

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

Date and time of submission

23 APR 2021 13:53:57

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

Date and time of submission

30 APR 2021 05:47:53

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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°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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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°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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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°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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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°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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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20 MAR 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 APR 2022 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

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17 APR 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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°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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 SEP 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**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°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 ☐

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59

US3112365

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:13:11

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		22 MAR 2021 13:35:31

US3112365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:59:30

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:59:30

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3112365

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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

Visit date (dd MMM yyyy)	22 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 09:59
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)	59 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)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112365

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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.*

US3112365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

10:05 (24 HR)

Collection date and time (derived)

22 MAR 2021 10:05

US3112365

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112365

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 21:05:10

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:05:09

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112365

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

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*

**US3112365**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:13:11**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112365

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:13:11

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"/>

US3112365

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:13:11

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3112365

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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

Visit date (dd MMM yyyy)	04 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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US3112365

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

Form: Unblinding

Data signed: (b) (4) 15 Apr 2021 23:40:40

Generated On: 09 Jun 2021 15:13:11

Date of updated informed consent ( <i>dd MMM yyyy</i> )	4 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> )	4 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



US3112365

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Height	70.5 in
Weight	231 lb
BMI (xxx.x)	32.74490

US3112365

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Height	70.5 in
Weight	231 lb
BMI (xxx.x)	32.74490
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)	4 JAN 2021
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 11:07
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3112365

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Height	70.5 in
Weight	231 lb
BMI (xxx.x)	32.74490
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)	4 JAN 2021
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 12:05
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3112365

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

4 JAN 2021

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

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US3112365

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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) 4 JAN 2021

What was the treatment time? (00:00-23:59) 11:34 (24 HR)

Treatment Date and Time (derived) 4 JAN 2021 11:34

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

US3112365

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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

Collection date (dd MMM yyyy)	4 JAN 2021
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Collection time (00:00-23:59)	11:21 (24 HR)
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Collection date and time (derived)	4 JAN 2021 11:21
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US3112365

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	11:12
Collection Date and Time (derived)	4 JAN 2021 11:12

US3112365

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112365

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3112365

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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

Visit date (dd MMM yyyy)	29 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	OLD29
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US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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)	29 JAN 2021
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 10:59
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 mmHg
Diastolic Blood Pressure units	MMHG

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 JAN 2021
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 12:10
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 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)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3112365

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

29 JAN 2021

---

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

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US3112365

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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) 29 JAN 2021

What was the treatment time? (00:00-23:59) 11:39 (24 HR)

Treatment Date and Time (derived) 29 JAN 2021 11:39

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112365

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3112365

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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

Visit date (dd MMM yyyy)	3 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
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US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	3 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:13 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 10:13
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112365

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

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.*

US3112365

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	10:23 (24 HR)
Collection date and time (derived)	3 MAR 2021 10:23

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:33:03

Generated On: 09 Jun 2021 15:13:11

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:33:03

Generated On: 09 Jun 2021 15:13:11

AEID	USA-US062-2020-MRNA-1273-P30 1000008
Adverse event	T12 FRACTURE
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)	28 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	06 NOV 2020
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 (1)

Data signed: (b) (4) 19 Mar 2021 20:33:03

Generated On: 09 Jun 2021 15:13:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:33:03

Generated On: 09 Jun 2021 15:13:11

---

PT EXPERIENCED  
MECHANICAL FALL FROM A  
LADDER, FRACTURING  
VERTEBRAE T12. PATIENT  
DENIED HOSPITAL VISIT UNTIL  
02NOV2020 WHEN PATIENT  
EXPERIENCED HEMATURIA.  
PATIENT THEN RECIEVED  
DIAGNOSIS OF FRACTURE AND  
WAS OPERATED ON THAT DAY.  
PT REMAINED IN PATIENT AT  
SCRIPPS ENCINITAS FOR  
MONITORING POST-OP UNTIL  
06NOV2020.  
NOTE: THE EVENT TERM T12  
FRACTURE IS AN UPDATED  
TERM OF T12 FRACTURE  
SECONDARY TO MECHANICAL  
FALL PER QUERY RESOLUTION

---

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

---

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:33:03

Generated On: 09 Jun 2021 15:13:11

AEID

Adverse event

CELLULITIS LOWER LEFT  
EXTREMITY

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)

27 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 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 ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:33:03

Generated On: 09 Jun 2021 15:13:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

---

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

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 (3)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication QVAR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input 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) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication PRO AIR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 1-2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input 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) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA VIRUS  
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication T12 FRACTURE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 02 NOV 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication DILAUDID

Prophylaxis Yes ☐  
No ☒

Indication T12 FRACTURE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication T12 FRACTURE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication TDAP

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication NACL 9%

Prophylaxis Yes ☐  
No ☒

Indication T12 FRACTURE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐  
No ☒

Indication T12 FRACTURE

Dose per administration 350/100

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 02 NOV 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication KEFLEX

Prophylaxis Yes ☐  
No ☒

Indication CELLULITIS LLE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	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)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication CELLULITIS LLE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication CELLULITIS LLE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication MOTRIN

Prophylaxis Yes ☐  
No ☒

Indication CELLULITIS LLE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication ROCEPHIN

Prophylaxis Yes ☐  
No ☒

Indication CELLULITIS LLE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐  
No ☒

Indication CELLULITIS LLE

Dose per administration 350

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)



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 21:57:16

Generated On: 09 Jun 2021 15:13:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 21:05:09

Generated On: 09 Jun 2021 15:13:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 NOV 2020	CT ABDOMEN WITH CONTRAST	Adverse Event	
02 NOV 2020	CT 2D RECONSTRUCTION	Adverse Event	
02 NOV 2020	CHEST XRAY	Adverse Event	
02 NOV 2020	THORACIC MRI WITHOUT CONTRAST	Adverse Event	
27 NOV 2020	COVID-19 RAPID TEST	Adverse Event	
27 NOV 2020	ECG	Adverse Event	
02 NOV 2020	COVID-19 RAPID TEST	Adverse Event	

US3112365

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:13:11

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

US3112365

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:13:11

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 ☐

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

SAEID	USA-US062-2020-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

SAEID	USA-US062-2020-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/NOV/2020 15:13
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

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

SAEID	USA-US062-2020-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/NOV/2020 11:24
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



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

SAEID	USA-US062-2020-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/DEC/2020 09:06
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

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

SAEID	USA-US062-2020-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	14/DEC/2020 16:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

SAEID	USA-US062-2020-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/DEC/2020 14:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 21:57:17

Generated On: 09 Jun 2021 15:13:11

SAEID	USA-US062-2020-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/DEC/2020 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.	True

Audit

US3112365 (Prod: Medical Center For Clinical Research - M3 Wake Research)

**US3112365**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:13:11**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'US3112365'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 21:59:24

US3112365

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:20

US3112365

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 21:59:25



US3112365

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:20

**US3112365**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:13:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'SCRN'	System	24 Aug 2020 23:41:20

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 21:59:26

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '69'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

**US3112365**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:13:11**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'YEARS'	System	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '69'	System	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24



US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24



US3112365

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:30:24

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Aug 2020'	System	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2020'	System	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:32



**US3112365**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:13:11**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:32

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 21:59:25

US3112365

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'I'	System	24 Aug 2020 23:41:38

US3112365

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:38

US3112365

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:13:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 03:10:24
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	08 Sep 2020 20:54:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 20:54:49
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:20:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:23:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:23:18

US3112365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:56:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:56:54
Data point term sent to Coder	System	08 Sep 2020 20:56:12
User entered 'Asthma'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:13

US3112365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2012'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:13

US3112365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:13



US3112365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:13

US3112365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:13

US3112365

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:13

**US3112365**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2012'	System	08 Sep 2020 20:55:13

**US3112365**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2012'	System	08 Sep 2020 20:55:13

**US3112365**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:55:13

**US3112365**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:55:13

US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:56:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:56:53
Data point term sent to Coder	System	08 Sep 2020 20:56:13
User entered 'Hypertension'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:31



US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN UNK 2003' reason for change: Data Entry Error	System	08 Sep 2020 20:55:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:37
User entered 'U UNK 2003' (non-conformant).	(b) (4)	
	System	08 Sep 2020 20:55:31
	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:31
	(b) (4)	

US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:31

US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:31

US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:31

US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:55:31

US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2003'	System	08 Sep 2020 20:55:37
User entered empty.	System	08 Sep 2020 20:55:31

US3112365

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2003'	System	08 Sep 2020 20:55:37
User entered empty.	System	08 Sep 2020 20:55:31

**US3112365**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:55:31



**US3112365**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:55:31

US3112365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:56:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:56:53
Data point term sent to Coder	System	08 Sep 2020 20:56:14
User entered 'Hypercholesterolemia'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:00

US3112365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2003'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:00

**US3112365**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:00

**US3112365**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:00

US3112365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:00

US3112365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:00

**US3112365**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2003'	System	08 Sep 2020 20:56:00



US3112365

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2003'	System	08 Sep 2020 20:56:00

**US3112365**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:56:00

**US3112365**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:56:00

US3112365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Sep 2020 20:57:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:57:59
Data point term sent to Coder	System	08 Sep 2020 20:57:15
User entered 'Acid reflux'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:20
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 1987'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:20

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:20

US3112365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:20

US3112365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:20



US3112365

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:20

**US3112365**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 1987'	System	08 Sep 2020 20:56:20

**US3112365**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '1987'	System	08 Sep 2020 20:56:20

**US3112365**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:56:20

**US3112365**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:56:20

US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
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)	08 Sep 2020 20:57:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:57:58
Data point term sent to Coder	System	08 Sep 2020 20:57:16
User entered 'Prostate cancer'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:57

US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2002'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:57

US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:57



US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'No (N)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:57

US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2002'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:57

US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:56:57

US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2002'	System	08 Sep 2020 20:56:57

**US3112365**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2002'	System	08 Sep 2020 20:56:57

US3112365

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2002'	System	08 Sep 2020 20:56:57

**US3112365**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2002'	System	08 Sep 2020 20:56:57

US3112365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:58:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:58:54
Data point term sent to Coder	System	08 Sep 2020 20:58:17
User entered 'Osteoarthritis-bilateral knees'	Karen Mylerberg (b) (4)	08 Sep 2020 20:57:30



US3112365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2010'	Karen Mylerberg (b) (4)	08 Sep 2020 20:57:30

US3112365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:57:30

US3112365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:57:30

US3112365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	Karen Mylerberg (b) (4)	08 Sep 2020 20:57:30

US3112365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:57:30

**US3112365**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2010'	System	08 Sep 2020 20:57:30

**US3112365**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2010'	System	08 Sep 2020 20:57:30

**US3112365**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:57:30



US3112365

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:57:30

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:58:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:58:53
Data point term sent to Coder	System	08 Sep 2020 20:58:17
User entered 'fatty liver'	Karen Mylerberg (b) (4)	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2019'	Karen Mylerberg (b) (4)	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	Karen Mylerberg (b) (4)	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2019'	System	08 Sep 2020 20:58:00



**US3112365**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2019'	System	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:58:00

**US3112365**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	08 Sep 2020 20:58:00

US3112365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 21:00:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 21:00:54
Data point term sent to Coder	System	08 Sep 2020 21:00:19
User entered 'Cholelithiasis'	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:32

US3112365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:32

US3112365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:32

US3112365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:47
User entered 'Yes (Y)'	(b) (4)	
	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:32
	(b) (4)	

US3112365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:47
User entered empty.	(b) (4)	
	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:32
	(b) (4)	



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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 20:59:32

US3112365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2015'	System	08 Sep 2020 20:59:32

**US3112365**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2015'	System	08 Sep 2020 20:59:32

US3112365

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2015'	System	08 Sep 2020 20:59:47
User entered empty.	System	08 Sep 2020 20:59:32

**US3112365**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2015'	System	08 Sep 2020 20:59:47
User entered empty.	System	08 Sep 2020 20:59:32

US3112365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 21:00:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 21:00:54
Data point term sent to Coder	System	08 Sep 2020 21:00:19
User entered 'Cholecystectomy'	Karen Mylerberg (b) (4)	08 Sep 2020 21:00:08

US3112365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	08 Sep 2020 21:00:08

US3112365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 21:00:08



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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'No (N)'	Karen Mylerberg (b) (4)	08 Sep 2020 21:00:08

US3112365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	08 Sep 2020 21:00:08

**US3112365**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:13:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Karen Mylerberg (b) (4)	08 Sep 2020 21:00:08

US3112365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2015'	System	08 Sep 2020 21:00:08

US3112365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2015'	System	08 Sep 2020 21:00:08

US3112365

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2015'	System	08 Sep 2020 21:00:08

**US3112365**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2015'	System	08 Sep 2020 21:00:08

US3112365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Nov 2020 00:55:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 00:55:08
Data point term sent to Coder	System	20 Nov 2020 00:54:38
User entered 'GERD'	Matthew Musikanth (b) (4)	20 Nov 2020 00:53:58



US3112365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'un UNK 2005'	(b) (4) Matthew Musikanth (b) (4)	20 Nov 2020 00:53:58

US3112365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	Matthew Musikanth (b) (4)	20 Nov 2020 00:53:58

US3112365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	20 Nov 2020 00:53:58

US3112365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	(b) (4) Matthew Musikanth	20 Nov 2020 00:53:58
	(b) (4)	

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	20 Nov 2020 00:53:58

US3112365

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2005'	System	20 Nov 2020 00:53:58

**US3112365**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2005'	System	20 Nov 2020 00:53:58

**US3112365**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	20 Nov 2020 00:53:58



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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	20 Nov 2020 00:53:58

US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User closed query 'Per MM: Please confirm OSA stands for obstructive sleep apnea.' (Site from DM).	(b) (4)	
Query 'Per MM: Please confirm OSA stands for obstructive sleep apnea.' answered with 'OSA stands for obstructive sleep apnea. condition has been updated in EDC ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:10:41
Query 'Per MM: Please confirm OSA stands for obstructive sleep apnea.' answered with 'OSA stands for obstructive sleep apnea. condition has been updated in EDC ' (Site from DM).	Brenda Grande (b) (4)	17 Dec 2020 00:08:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Dec 2020 00:06:23
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	17 Dec 2020 00:05:30
	Brenda Grande (b) (4)	17 Dec 2020 00:05:26
	(b) (4)	
User entered 'obstructive sleep apnea' reason for change: Data Entry Error	Brenda Grande (b) (4)	17 Dec 2020 00:05:26
User opened query 'Per MM: Please confirm OSA stands for obstructive sleep apnea.' (Site from DM).	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	(b) (4), (b) (6)	14 Dec 2020 23:07:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 00:55:08
Data point term sent to Coder	(b) (4)	
User entered 'OSA'	Coder Import (b) (4)	20 Nov 2020 00:55:08
	(b) (4)	
	System	20 Nov 2020 00:54:38
	Matthew Musikanth	20 Nov 2020 00:54:23
	(b) (4)	

US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'un UNK 2014'	(b) (4) Matthew Musikanth (b) (4)	20 Nov 2020 00:54:23

US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	20 Nov 2020 00:54:23

US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	20 Nov 2020 00:54:23

US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered empty.	(b) (4) Matthew Musikanth	20 Nov 2020 00:54:23
	(b) (4)	

US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	20 Nov 2020 00:54:23

**US3112365**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'Jan 2014'	System	20 Nov 2020 00:54:23



US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '2014'	System	20 Nov 2020 00:54:23

US3112365

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	20 Nov 2020 00:54:23

**US3112365**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered empty.	System	20 Nov 2020 00:54:23

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '14:55'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered '24 Aug 2020 14:55'	System	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '70' in	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:04
DataPoint set to visible.	System	24 Aug 2020 23:41:38



US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '236' lb	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:04
DataPoint set to visible.	System	24 Aug 2020 23:41:38

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
Amendment Manager: User entered '33.93328'	System	17 Sep 2020 00:22:07
User entered '33.9'	System	25 Aug 2020 19:33:04
DataPoint set to visible.	System	24 Aug 2020 23:41:38

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'kg/m2'	System	25 Aug 2020 19:33:04
DataPoint set to visible.	System	24 Aug 2020 23:41:38

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:40:47
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' answered with 'Updated ' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 03:22:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 03:22:11
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 11:11:17
User entered '98.2' F	(b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	06 Sep 2020 03:22:11
User entered 'Oral (Oral)'	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:22:11
User entered '73'	(b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'bpm'	System	25 Aug 2020 19:33:04



US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:22:11
User entered '16'	(b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'breaths/min'	System	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:22:11
User entered '128'	(b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'mmHg'	System	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:22:11
User entered '81'	(b) (4), (b) (6)	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User entered 'mmHg'	System	25 Aug 2020 19:33:04

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53

US3112365

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53



US3112365

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:34:10

US3112365

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:30
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:34:10

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36



US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36



US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

**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 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:12:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:31:36

US3112365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:52



US3112365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:52

US3112365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:41:52

US3112365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'VISIT1'	System	24 Aug 2020 23:41:52

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 23:04:14

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '187689'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 23:04:14

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 23:04:14

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:24:28

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:24:28



US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:24:28

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:24:28

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:24:28

US3112365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:11

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:34:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:46:21

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32



US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '14:55'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '24 Aug 2020 14:55'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32



US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '73'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'bpm'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'breaths/min'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '128'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '81'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	25 Aug 2020 19:32:32



US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '16:59'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '24 Aug 2020 16:59'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32



US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '74'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'bpm'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'breaths/min'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '144'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	25 Aug 2020 19:32:32



US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '76'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	25 Aug 2020 19:32:32

US3112365

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:28

US3112365

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:28

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 23:42:16



US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '16:28'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '24 Aug 2020 16:28'	System	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'ONCE'	System	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 23:42:16

US3112365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:15

US3112365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:15



US3112365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '15:03'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:15

US3112365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '24 Aug 2020 15:03'	System	25 Aug 2020 19:33:15

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:13:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '13:57'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '24 Aug 2020 13:57'	System	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Aug 2020 19:33:58



US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered empty.	System	25 Aug 2020 19:33:58

US3112365

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:42:34

US3112365

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	24 Aug 2020 23:42:34

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T16:59:58', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3017b528-18f5-4302-8b84-758aa150ddf4' User entered 'Yes (Y)'	System	25 Aug 2020 00:00:26
	System	25 Aug 2020 00:00:26

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:00:09', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3017b528-18f5-4302-8b84-758aa150ddf4' User entered '98.1'	System	25 Aug 2020 00:00:26
	System	25 Aug 2020 00:00:26



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:00:17', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3017b528-18f5-4302-8b84-758aa150ddf4'	System	25 Aug 2020 00:00:26
User entered 'No (N)'	System	25 Aug 2020 00:00:26

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:00:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3017b528-18f5-4302-8b84-758aa150ddf4'	System	25 Aug 2020 00:00:26
User entered '24 Aug 2020 17:00'	System	25 Aug 2020 00:00:26

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 16:48'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 19:18'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 20:13'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 2'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:10', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f87dd415-f1bd-452c-9ff1-e5398a812649' User entered 'Yes (Y)'	System	25 Aug 2020 21:28:45
	System	25 Aug 2020 21:28:45

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:19', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f87dd415-f1bd-452c-9ff1-e5398a812649' User entered '98.1'	System	25 Aug 2020 21:28:45
	System	25 Aug 2020 21:28:45



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:24', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f87dd415-f1bd-452c-9ff1-e5398a812649'	System	25 Aug 2020 21:28:45
User entered 'No (N)'	System	25 Aug 2020 21:28:45

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:35', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f87dd415-f1bd-452c-9ff1-e5398a812649' User entered '25 Aug 2020 14:28'	System	25 Aug 2020 21:28:45
	System	25 Aug 2020 21:28:45

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 3'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:53:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'da35b1a3-58e7-407e-af21-d6a8f8d8eb8a' User entered 'Yes (Y)'	System	26 Aug 2020 19:54:03
	System	26 Aug 2020 19:54:03

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:53:52', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'da35b1a3-58e7-407e-af21-d6a8f8d8eb8a' User entered '97.7'	System	26 Aug 2020 19:54:03
	System	26 Aug 2020 19:54:03

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:53:56', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'da35b1a3-58e7-407e-af21-d6a8f8d8eb8a'	System	26 Aug 2020 19:54:03
User entered 'No (N)'	System	26 Aug 2020 19:54:03



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:01', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'da35b1a3-58e7-407e-af21-d6a8f8d8eb8a' User entered '26 Aug 2020 12:54'	System	26 Aug 2020 19:54:03
	System	26 Aug 2020 19:54:03

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 4'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:20', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0d6eee58-ce45-413b-a257-b0170ff1d4b9' User entered 'Yes (Y)'	System	27 Aug 2020 21:07:35
	System	27 Aug 2020 21:07:35

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0d6eee58-ce45-413b-a257-b0170ff1d4b9' User entered '98.6'	System	27 Aug 2020 21:07:35
	System	27 Aug 2020 21:07:35

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:29', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0d6eee58-ce45-413b-a257-b0170ff1d4b9' User entered 'No (N)'	System	27 Aug 2020 21:07:35
	System	27 Aug 2020 21:07:35

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:33', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0d6eee58-ce45-413b-a257-b0170ff1d4b9' User entered '27 Aug 2020 14:07'	System	27 Aug 2020 21:07:35
	System	27 Aug 2020 21:07:35



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 5'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:01', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1d601686-b257-4028-95e8-83692838a683' User entered 'Yes (Y)'	System	28 Aug 2020 20:12:20
	System	28 Aug 2020 20:12:20

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:07', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1d601686-b257-4028-95e8-83692838a683' User entered '98.3'	System	28 Aug 2020 20:12:20
	System	28 Aug 2020 20:12:20

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:13', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1d601686-b257-4028-95e8-83692838a683' User entered 'No (N)'	System	28 Aug 2020 20:12:20
	System	28 Aug 2020 20:12:20

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:16', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1d601686-b257-4028-95e8-83692838a683' User entered '28 Aug 2020 13:12'	System	28 Aug 2020 20:12:20
	System	28 Aug 2020 20:12:20

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 6'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:52:07', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '44d1bbe2-163a-4398-935f-6e81e110207a' User entered 'Yes (Y)'	System	29 Aug 2020 22:52:37
	System	29 Aug 2020 22:52:37

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:52:23', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '44d1bbe2-163a-4398-935f-6e81e110207a' User entered '98.5'	System	29 Aug 2020 22:52:37
	System	29 Aug 2020 22:52:37

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:52:29', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '44d1bbe2-163a-4398-935f-6e81e110207a' User entered 'No (N)'	System	29 Aug 2020 22:52:37
	System	29 Aug 2020 22:52:37

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:52:33', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '44d1bbe2-163a-4398-935f-6e81e110207a' User entered '29 Aug 2020 15:52'	System	29 Aug 2020 22:52:37
	System	29 Aug 2020 22:52:37

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 7'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:03', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'edbee8e1-213d-4cf5-9d62-adeccab516c2' User entered 'Yes (Y)'	System	30 Aug 2020 22:16:19
	System	30 Aug 2020 22:16:19

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:09', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'edbee8e1-213d-4cf5-9d62-adeccab516c2' User entered '98.5'	System	30 Aug 2020 22:16:19
	System	30 Aug 2020 22:16:19

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:12', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'edbee8e1-213d-4cf5-9d62-adeccab516c2'	System	30 Aug 2020 22:16:19
User entered 'No (N)'	System	30 Aug 2020 22:16:19

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:16', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'edbee8e1-213d-4cf5-9d62-adeccab516c2' User entered '30 Aug 2020 15:16'	System	30 Aug 2020 22:16:19
	System	30 Aug 2020 22:16:19

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:00:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1cadd67-694a-4519-b09f-32481ddb65c2'	System	25 Aug 2020 00:01:15
User entered 'None (1)'	System	25 Aug 2020 00:01:15

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:00:48', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1cadd67-694a-4519-b09f-32481ddb65c2'	System	25 Aug 2020 00:01:15
User entered 'No (N)'	System	25 Aug 2020 00:01:15

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:00:57', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1cadd67-694a-4519-b09f-32481ddb65c2'	System	25 Aug 2020 00:01:15
User entered 'No (N)'	System	25 Aug 2020 00:01:15

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:06', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1cadd67-694a-4519-b09f-32481ddb65c2'	System	25 Aug 2020 00:01:15
User entered 'None (1)'	System	25 Aug 2020 00:01:15

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:12', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1cadd67-694a-4519-b09f-32481ddb65c2' User entered '24 Aug 2020 17:01'	System	25 Aug 2020 00:01:15
	System	25 Aug 2020 00:01:15

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 16:48'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 19:18'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 20:13'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 2'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:44', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '8749ee5e-3e24-40e7-b014-7dd5a45018b7'	System	25 Aug 2020 21:29:06
User entered 'None (1)'	System	25 Aug 2020 21:29:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:47', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '8749ee5e-3e24-40e7-b014-7dd5a45018b7' User entered 'No (N)'	System	25 Aug 2020 21:29:06
	System	25 Aug 2020 21:29:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:50', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '8749ee5e-3e24-40e7-b014-7dd5a45018b7' User entered 'No (N)'	System	25 Aug 2020 21:29:06
	System	25 Aug 2020 21:29:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:28:57', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '8749ee5e-3e24-40e7-b014-7dd5a45018b7' User entered 'None (1)'	System	25 Aug 2020 21:29:06
	System	25 Aug 2020 21:29:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:03', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '8749ee5e-3e24-40e7-b014-7dd5a45018b7' User entered '25 Aug 2020 14:29'	System	25 Aug 2020 21:29:06
	System	25 Aug 2020 21:29:06

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 3'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:05', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '97659f0d-e989-4163-afcf-61b0494dfb84'	System	26 Aug 2020 19:54:24
User entered 'None (1)'	System	26 Aug 2020 19:54:24

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:08', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '97659f0d-e989-4163-afcf-61b0494dfb84'	System	26 Aug 2020 19:54:24
User entered 'No (N)'	System	26 Aug 2020 19:54:24

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:16', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '97659f0d-e989-4163-afcf-61b0494dfb84'	System	26 Aug 2020 19:54:24
User entered 'No (N)'	System	26 Aug 2020 19:54:24

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:20', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '97659f0d-e989-4163-afcf-61b0494dfb84'	System	26 Aug 2020 19:54:24
User entered 'None (1)'	System	26 Aug 2020 19:54:24

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:23', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '97659f0d-e989-4163-afcf-61b0494dfb84' User entered '26 Aug 2020 12:54'	System	26 Aug 2020 19:54:24
	System	26 Aug 2020 19:54:24

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 4'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:43', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'b3ca57ba-fb91-4883-9e07-f18c16b88579' User entered 'None (1)'	System	27 Aug 2020 21:08:04
	System	27 Aug 2020 21:08:04

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:46', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'b3ca57ba-fb91-4883-9e07-f18c16b88579' User entered 'No (N)'	System	27 Aug 2020 21:08:04
	System	27 Aug 2020 21:08:04

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:51', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'b3ca57ba-fb91-4883-9e07-f18c16b88579' User entered 'No (N)'	System	27 Aug 2020 21:08:04
	System	27 Aug 2020 21:08:04

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:56', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'b3ca57ba-fb91-4883-9e07-f18c16b88579' User entered 'None (1)'	System	27 Aug 2020 21:08:04
	System	27 Aug 2020 21:08:04

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:07:59', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'b3ca57ba-fb91-4883-9e07-f18c16b88579' User entered '27 Aug 2020 14:07'	System	27 Aug 2020 21:08:04
	System	27 Aug 2020 21:08:04

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 5'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:11:34', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '22dac0ef-183d-4fdd-aef0-b55ff0ab45b8'	System	28 Aug 2020 20:11:49
User entered 'None (1)'	System	28 Aug 2020 20:11:49

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:11:37', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '22dac0ef-183d-4fdd-aef0-b55ff0ab45b8'	System	28 Aug 2020 20:11:49
User entered 'No (N)'	System	28 Aug 2020 20:11:49

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:11:39', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '22dac0ef-183d-4fdd-aef0-b55ff0ab45b8'	System	28 Aug 2020 20:11:49
User entered 'No (N)'	System	28 Aug 2020 20:11:49

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:11:44', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '22dac0ef-183d-4fdd-aef0-b55ff0ab45b8'	System	28 Aug 2020 20:11:49
User entered 'None (1)'	System	28 Aug 2020 20:11:49

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:11:48', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '22dac0ef-183d-4fdd-aef0-b55ff0ab45b8' User entered '28 Aug 2020 13:11'	System	28 Aug 2020 20:11:49
	System	28 Aug 2020 20:11:49

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 6'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:52:43', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '29e2af6d-4673-4caf-9162-4814240fc666'	System	29 Aug 2020 22:53:08
User entered 'None (1)'	System	29 Aug 2020 22:53:08

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:52:47', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '29e2af6d-4673-4caf-9162-4814240fc666'	System	29 Aug 2020 22:53:08
User entered 'No (N)'	System	29 Aug 2020 22:53:08

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:52:51', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '29e2af6d-4673-4caf-9162-4814240fc666'	System	29 Aug 2020 22:53:08
User entered 'No (N)'	System	29 Aug 2020 22:53:08

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:03', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '29e2af6d-4673-4caf-9162-4814240fc666'	System	29 Aug 2020 22:53:08
User entered 'None (1)'	System	29 Aug 2020 22:53:08

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:06', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '29e2af6d-4673-4caf-9162-4814240fc666' User entered '29 Aug 2020 15:53'	System	29 Aug 2020 22:53:08
	System	29 Aug 2020 22:53:08

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 7'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:19', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d6470d6-1e47-4721-a890-d3997f83911b' User entered 'None (1)'	System	30 Aug 2020 22:16:34
	System	30 Aug 2020 22:16:34

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:22', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d6470d6-1e47-4721-a890-d3997f83911b' User entered 'No (N)'	System	30 Aug 2020 22:16:34
	System	30 Aug 2020 22:16:34

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d6470d6-1e47-4721-a890-d3997f83911b' User entered 'No (N)'	System	30 Aug 2020 22:16:34
	System	30 Aug 2020 22:16:34

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:28', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d6470d6-1e47-4721-a890-d3997f83911b' User entered 'None (1)'	System	30 Aug 2020 22:16:34
	System	30 Aug 2020 22:16:34

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:30', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d6470d6-1e47-4721-a890-d3997f83911b' User entered '30 Aug 2020 15:16'	System	30 Aug 2020 22:16:34
	System	30 Aug 2020 22:16:34

US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:22', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6' User entered 'None (0)'	System	25 Aug 2020 00:01:57
	System	25 Aug 2020 00:01:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:26', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6' User entered 'None (0)'	System	25 Aug 2020 00:01:57
	System	25 Aug 2020 00:01:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:29', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6' User entered 'None (0)'	System	25 Aug 2020 00:01:57
	System	25 Aug 2020 00:01:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:32', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6' User entered 'None (0)'	System	25 Aug 2020 00:01:57
	System	25 Aug 2020 00:01:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:35', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6' User entered 'None (0)'	System	25 Aug 2020 00:01:57
	System	25 Aug 2020 00:01:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:38', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6' User entered 'None (0)'	System	25 Aug 2020 00:01:57
	System	25 Aug 2020 00:01:57



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:49', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6'	System	25 Aug 2020 00:01:57
User entered 'No (N)'	System	25 Aug 2020 00:01:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-24T17:01:55', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2eaa2687-3293-471f-84c2-0041ea927ea6' User entered '24 Aug 2020 17:01'	System	25 Aug 2020 00:01:57
	System	25 Aug 2020 00:01:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 16:48'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 19:18'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Aug 2020 20:13'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 2'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:08', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered 'None (0)'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:11', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered 'None (0)'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:15', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered 'None (0)'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:18', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered 'None (0)'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:21', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered 'None (0)'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:24', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered 'None (0)'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:28', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered 'No (N)'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-25T14:29:32', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a8ce1ab5-4d95-4a9f-b3c5-3265c7292121' User entered '25 Aug 2020 14:29'	System	25 Aug 2020 21:29:37
	System	25 Aug 2020 21:29:37



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 3'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:29', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered 'None (0)'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:31', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered 'None (0)'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:34', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered 'None (0)'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:37', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered 'None (0)'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered 'None (0)'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:43', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered 'None (0)'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:53', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered 'No (N)'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-26T12:54:56', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd613f747-712e-4141-ab07-f26af13f0740' User entered '26 Aug 2020 12:54'	System	26 Aug 2020 19:54:57
	System	26 Aug 2020 19:54:57

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 4'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:06', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered 'None (0)'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:09', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered 'None (0)'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:12', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered 'None (0)'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:16', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered 'None (0)'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:19', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered 'None (0)'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:21', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered 'None (0)'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered 'No (N)'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-27T14:08:28', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3918b74b-1162-4eeb-8b99-36624392872c' User entered '27 Aug 2020 14:08'	System	27 Aug 2020 21:08:32
	System	27 Aug 2020 21:08:32

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 5'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:22', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered 'None (0)'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered 'None (0)'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:29', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered 'None (0)'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:31', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered 'None (0)'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:34', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered 'None (0)'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:37', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered 'None (0)'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered 'No (N)'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-28T13:12:43', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c37296ca-450e-4af4-83fb-53ee99edbac0' User entered '28 Aug 2020 13:12'	System	28 Aug 2020 20:12:45
	System	28 Aug 2020 20:12:45

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 6'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:11', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered 'None (0)'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:27', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered 'None (0)'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:30', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered 'None (0)'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:33', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered 'None (0)'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:36', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered 'None (0)'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:39', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered 'None (0)'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:42', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered 'No (N)'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-29T15:53:46', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba7c3a37-6543-45d4-b7de-04546529c7d0' User entered '29 Aug 2020 15:53'	System	29 Aug 2020 22:53:50
	System	29 Aug 2020 22:53:50

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 7'	System	24 Aug 2020 23:42:16

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:35', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered 'None (0)'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:37', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered 'None (0)'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered 'None (0)'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:42', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered 'None (0)'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:45', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered 'None (0)'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:49', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered 'None (0)'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:55', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered 'No (N)'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-08-30T15:16:57', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3424e690-ecb1-4b67-aff1-8f75b21b8545' User entered '30 Aug 2020 15:16'	System	30 Aug 2020 22:16:59
	System	30 Aug 2020 22:16:59

US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 23:42:16



US3112365

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 23:06:21

US3112365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 23:06:21

US3112365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 23:06:21

US3112365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 23:06:21

US3112365

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 23:06:30

US3112365

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	31 Aug 2020 23:06:30

US3112365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:54:05



US3112365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered '8 Sep 2020'	Karen Mylerberg (b) (4)	08 Sep 2020 20:54:05

US3112365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:54:05

US3112365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered empty.	Karen Mylerberg (b) (4)	08 Sep 2020 20:54:05

US3112365

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Sep 2020 20:54:11

US3112365

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	08 Sep 2020 20:54:11

US3112365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	Natalie Moy (b) (4)	12 Oct 2020 20:27:28

US3112365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered '15 Sep 2020'	Natalie Moy (b) (4)	12 Oct 2020 20:27:28

US3112365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:27:28



US3112365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered empty.	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:27:28

US3112365

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:24:39

US3112365

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	21 Sep 2020 18:24:39

US3112365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:24:50

US3112365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:24:50

US3112365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:24:50

US3112365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'VISIT2'	System	21 Sep 2020 18:24:50

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23
	(b) (4)	



US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '21 Sep 2020'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '10:25'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '21 Sep 2020 10:25'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '98.1' F	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '63'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23



US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'bpm'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '16'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'breaths/min'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '132'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '079'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23



US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '21 Sep 2020'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '11:45'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '21 Sep 2020 11:45'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '98.7' F	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '64'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23



US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'bpm'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '14'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'breaths/min'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '148'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '088'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	22 Sep 2020 14:29:23

US3112365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 19:40:03
User entered 'No (N)'	(b) (4)	
	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:30
	(b) (4)	



US3112365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 19:40:03
User entered empty.	(b) (4)	
	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:30
	(b) (4)	

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '11:14'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '21 Sep 2020 11:14'	System	21 Sep 2020 18:25:06



US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'ONCE'	System	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 18:25:06

US3112365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:44

US3112365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '21 Sep 2020'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:44

US3112365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '10:50'	Karen Mylerberg (b) (4)	22 Sep 2020 14:29:44

US3112365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '21 Sep 2020 10:50'	System	22 Sep 2020 14:29:44

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:13:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '21 Sep 2020'	Karen Mylerberg (b) (4)	22 Sep 2020 14:30:00



US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:30:00

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:30:00

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '10:40'	Karen Mylerberg (b) (4)	22 Sep 2020 14:30:00

**US3112365**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '21 Sep 2020 10:40'	System	22 Sep 2020 14:30:00

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:30:00

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	Karen Mylerberg (b) (4)	22 Sep 2020 14:30:00

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	Karen Mylerberg (b) (4)	22 Sep 2020 14:30:00

US3112365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered empty.	System	22 Sep 2020 14:30:00



US3112365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:25:11

US3112365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	21 Sep 2020 18:25:11

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:44:35', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0e160361-3a5f-4bf5-8cb1-567ae5a190e7' User entered 'Yes (Y)'	System	21 Sep 2020 18:45:02
	System	21 Sep 2020 18:45:02

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:44:47', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0e160361-3a5f-4bf5-8cb1-567ae5a190e7' User entered '98.7'	System	21 Sep 2020 18:45:02
	System	21 Sep 2020 18:45:02

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:44:51', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0e160361-3a5f-4bf5-8cb1-567ae5a190e7'	System	21 Sep 2020 18:45:02
User entered 'No (N)'	System	21 Sep 2020 18:45:02

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:44:57', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '0e160361-3a5f-4bf5-8cb1-567ae5a190e7' User entered '21 Sep 2020 11:44'	System	21 Sep 2020 18:45:02
	System	21 Sep 2020 18:45:02

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 11:34'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 14:04'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 14:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 2'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:21', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3ee726fe-4649-43f3-9ce9-ec4f03ed6b3e' User entered 'Yes (Y)'	System	23 Sep 2020 00:57:38
	System	23 Sep 2020 00:57:38

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:27', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3ee726fe-4649-43f3-9ce9-ec4f03ed6b3e' User entered '97.8'	System	23 Sep 2020 00:57:38
	System	23 Sep 2020 00:57:38

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:31', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3ee726fe-4649-43f3-9ce9-ec4f03ed6b3e' User entered 'No (N)'	System	23 Sep 2020 00:57:38
	System	23 Sep 2020 00:57:38

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:35', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '3ee726fe-4649-43f3-9ce9-ec4f03ed6b3e' User entered '22 Sep 2020 17:57'	System	23 Sep 2020 00:57:38
	System	23 Sep 2020 00:57:38

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 3'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:13', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6a456088-881e-46db-af41-02ccdb7acd27' User entered 'Yes (Y)'	System	23 Sep 2020 22:19:35
	System	23 Sep 2020 22:19:35

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:27', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6a456088-881e-46db-af41-02ccdb7acd27' User entered '98.1'	System	23 Sep 2020 22:19:35
	System	23 Sep 2020 22:19:35

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:30', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6a456088-881e-46db-af41-02ccdb7acd27'	System	23 Sep 2020 22:19:35
User entered 'No (N)'	System	23 Sep 2020 22:19:35

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:33', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6a456088-881e-46db-af41-02ccdb7acd27' User entered '23 Sep 2020 15:19'	System	23 Sep 2020 22:19:35
	System	23 Sep 2020 22:19:35

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 4'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:43:06', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1b6560ae-8102-4041-890d-9801cb30f2d7' User entered 'Yes (Y)'	System	25 Sep 2020 01:44:20
	System	25 Sep 2020 01:44:20

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:08', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1b6560ae-8102-4041-890d-9801cb30f2d7' User entered '97.0'	System	25 Sep 2020 01:44:20
	System	25 Sep 2020 01:44:20

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:12', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1b6560ae-8102-4041-890d-9801cb30f2d7'	System	25 Sep 2020 01:44:20
User entered 'No (N)'	System	25 Sep 2020 01:44:20

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:16', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '1b6560ae-8102-4041-890d-9801cb30f2d7' User entered '24 Sep 2020 18:44'	System	25 Sep 2020 01:44:20
	System	25 Sep 2020 01:44:20

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 5'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:20', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6ac1958b-6a73-4b92-a64e-e6f5ed3ad967' User entered 'Yes (Y)'	System	25 Sep 2020 21:05:40
	System	25 Sep 2020 21:05:40

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6ac1958b-6a73-4b92-a64e-e6f5ed3ad967' User entered '98.2'	System	25 Sep 2020 21:05:40
	System	25 Sep 2020 21:05:40

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:30', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6ac1958b-6a73-4b92-a64e-e6f5ed3ad967'	System	25 Sep 2020 21:05:40
User entered 'No (N)'	System	25 Sep 2020 21:05:40

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:33', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '6ac1958b-6a73-4b92-a64e-e6f5ed3ad967' User entered '25 Sep 2020 14:05'	System	25 Sep 2020 21:05:40
	System	25 Sep 2020 21:05:40

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 6'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 7'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:20:47', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f2635a0b-0f9d-45b4-8c8d-8b3c202397b1' User entered 'Yes (Y)'	System	27 Sep 2020 20:21:03
	System	27 Sep 2020 20:21:03

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:20:53', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f2635a0b-0f9d-45b4-8c8d-8b3c202397b1' User entered '98.1'	System	27 Sep 2020 20:21:03
	System	27 Sep 2020 20:21:03

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:20:56', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f2635a0b-0f9d-45b4-8c8d-8b3c202397b1' User entered 'No (N)'	System	27 Sep 2020 20:21:03
	System	27 Sep 2020 20:21:03

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:21:01', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f2635a0b-0f9d-45b4-8c8d-8b3c202397b1' User entered '27 Sep 2020 13:21'	System	27 Sep 2020 20:21:03
	System	27 Sep 2020 20:21:03

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:30', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '605f77d4-6e16-4deb-8e48-a1155aeff170'	System	21 Sep 2020 18:45:46
User entered 'None (1)'	System	21 Sep 2020 18:45:46



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:33', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '605f77d4-6e16-4deb-8e48-a1155aeff170' User entered 'No (N)'	System	21 Sep 2020 18:45:46
	System	21 Sep 2020 18:45:46

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:37', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '605f77d4-6e16-4deb-8e48-a1155aeff170' User entered 'No (N)'	System	21 Sep 2020 18:45:46
	System	21 Sep 2020 18:45:46

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '605f77d4-6e16-4deb-8e48-a1155aeff170' User entered 'None (1)'	System	21 Sep 2020 18:45:46
	System	21 Sep 2020 18:45:46

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:44', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '605f77d4-6e16-4deb-8e48-a1155aeff170' User entered '21 Sep 2020 11:45'	System	21 Sep 2020 18:45:46
	System	21 Sep 2020 18:45:46

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 11:34'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 14:04'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 14:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 2'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:45', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e0ea2bb1-2502-4e64-8559-5dd0f8413558'	System	23 Sep 2020 00:58:10
User entered 'None (1)'	System	23 Sep 2020 00:58:10

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:48', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e0ea2bb1-2502-4e64-8559-5dd0f8413558' User entered 'No (N)'	System	23 Sep 2020 00:58:10
	System	23 Sep 2020 00:58:10

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:50', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e0ea2bb1-2502-4e64-8559-5dd0f8413558' User entered 'No (N)'	System	23 Sep 2020 00:58:10
	System	23 Sep 2020 00:58:10

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:57:54', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e0ea2bb1-2502-4e64-8559-5dd0f8413558'	System	23 Sep 2020 00:58:10
User entered 'None (1)'	System	23 Sep 2020 00:58:10

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:08', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e0ea2bb1-2502-4e64-8559-5dd0f8413558' User entered '22 Sep 2020 17:58'	System	23 Sep 2020 00:58:10
	System	23 Sep 2020 00:58:10

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 3'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:38', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f7dc737e-4087-4131-9274-d1da7cc46e75'	System	23 Sep 2020 22:19:51
User entered 'None (1)'	System	23 Sep 2020 22:19:51

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f7dc737e-4087-4131-9274-d1da7cc46e75'	System	23 Sep 2020 22:19:51
User entered 'No (N)'	System	23 Sep 2020 22:19:51

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:43', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f7dc737e-4087-4131-9274-d1da7cc46e75' User entered 'No (N)'	System	23 Sep 2020 22:19:51
	System	23 Sep 2020 22:19:51

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:45', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f7dc737e-4087-4131-9274-d1da7cc46e75'	System	23 Sep 2020 22:19:51
User entered 'None (1)'	System	23 Sep 2020 22:19:51

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:48', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f7dc737e-4087-4131-9274-d1da7cc46e75'	System	23 Sep 2020 22:19:51
User entered '23 Sep 2020 15:19'	System	23 Sep 2020 22:19:51

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 4'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd95a99ea-f847-489d-bf41-7dfa385edd07'	System	25 Sep 2020 01:45:08
User entered 'None (1)'	System	25 Sep 2020 01:45:08

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:29', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd95a99ea-f847-489d-bf41-7dfa385edd07'	System	25 Sep 2020 01:45:08
User entered 'No (N)'	System	25 Sep 2020 01:45:08

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:32', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd95a99ea-f847-489d-bf41-7dfa385edd07'	System	25 Sep 2020 01:45:08
User entered 'No (N)'	System	25 Sep 2020 01:45:08

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd95a99ea-f847-489d-bf41-7dfa385edd07'	System	25 Sep 2020 01:45:08
User entered 'None (1)'	System	25 Sep 2020 01:45:08

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:44:53', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'd95a99ea-f847-489d-bf41-7dfa385edd07' User entered '24 Sep 2020 18:44'	System	25 Sep 2020 01:45:08
	System	25 Sep 2020 01:45:08

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 5'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:38', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '371b28f9-5c19-41c5-be52-25ecc7e5b89b' User entered 'None (1)'	System	25 Sep 2020 21:05:53
	System	25 Sep 2020 21:05:53

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '371b28f9-5c19-41c5-be52-25ecc7e5b89b' User entered 'No (N)'	System	25 Sep 2020 21:05:53
	System	25 Sep 2020 21:05:53

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:46', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '371b28f9-5c19-41c5-be52-25ecc7e5b89b' User entered 'No (N)'	System	25 Sep 2020 21:05:53
	System	25 Sep 2020 21:05:53

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:48', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '371b28f9-5c19-41c5-be52-25ecc7e5b89b' User entered 'None (1)'	System	25 Sep 2020 21:05:53
	System	25 Sep 2020 21:05:53

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:51', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '371b28f9-5c19-41c5-be52-25ecc7e5b89b' User entered '25 Sep 2020 14:05'	System	25 Sep 2020 21:05:53
	System	25 Sep 2020 21:05:53

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 6'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 7'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:21:05', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f9c3852f-2ba6-463b-9d4a-93ada8e2cc98'	System	27 Sep 2020 20:21:31
User entered 'None (1)'	System	27 Sep 2020 20:21:31

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:21:08', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f9c3852f-2ba6-463b-9d4a-93ada8e2cc98'	System	27 Sep 2020 20:21:31
User entered 'No (N)'	System	27 Sep 2020 20:21:31

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:21:15', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f9c3852f-2ba6-463b-9d4a-93ada8e2cc98'	System	27 Sep 2020 20:21:31
User entered 'No (N)'	System	27 Sep 2020 20:21:31

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:21:18', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f9c3852f-2ba6-463b-9d4a-93ada8e2cc98'	System	27 Sep 2020 20:21:31
User entered 'None (1)'	System	27 Sep 2020 20:21:31

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:21:28', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f9c3852f-2ba6-463b-9d4a-93ada8e2cc98'	System	27 Sep 2020 20:21:31
User entered '27 Sep 2020 13:21'	System	27 Sep 2020 20:21:31



US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:50', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered 'None (0)'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:54', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered 'None (0)'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:45:58', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered 'None (0)'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:46:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered 'None (0)'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:46:03', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered 'None (0)'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:46:05', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered 'None (0)'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:46:08', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered 'No (N)'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-21T11:46:11', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '52629c12-0999-4063-b191-4ed26bad1196' User entered '21 Sep 2020 11:46'	System	21 Sep 2020 18:46:14
	System	21 Sep 2020 18:46:14

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 11:34'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 14:04'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '21 Sep 2020 14:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 2'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:13', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered 'None (0)'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:15', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered 'None (0)'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:19', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered 'None (0)'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:21', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered 'None (0)'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:23', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered 'None (0)'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered 'None (0)'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:30', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered 'No (N)'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-22T17:58:32', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f619ea83-742b-46ce-8840-3c74be8dbe96' User entered '22 Sep 2020 17:58'	System	23 Sep 2020 00:58:36
	System	23 Sep 2020 00:58:36

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 3'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:51', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered 'None (0)'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:53', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered 'None (0)'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:55', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered 'None (0)'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:57', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered 'None (0)'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:19:59', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered 'None (0)'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:20:01', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered 'None (0)'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:20:04', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered 'No (N)'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-23T15:20:06', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '308e87cd-ea48-4977-9679-3b67ee73f816' User entered '23 Sep 2020 15:20'	System	23 Sep 2020 22:20:08
	System	23 Sep 2020 22:20:08

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 4'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered 'None (0)'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:03', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered 'None (0)'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:07', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered 'None (0)'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:14', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered 'None (0)'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:17', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered 'None (0)'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:19', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered 'None (0)'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:24', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered 'No (N)'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-24T18:45:27', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ecc457e9-4d9d-4232-9ae2-33336dbc2bd7' User entered '24 Sep 2020 18:45'	System	25 Sep 2020 01:45:31
	System	25 Sep 2020 01:45:31

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 5'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:55', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered 'None (0)'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:57', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered 'None (0)'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:05:59', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered 'None (0)'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:06:02', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered 'None (0)'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:06:04', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered 'None (0)'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:06:06', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered 'None (0)'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:06:10', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered 'No (N)'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53

**US3112365**

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

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:13:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-25T14:06:50', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '67c4df26-ec89-4d06-8a0f-69e3dc89b2b6' User entered '25 Sep 2020 14:06'	System	25 Sep 2020 21:06:53
	System	25 Sep 2020 21:06:53

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 6'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	21 Sep 2020 18:25:06
User entered 'Day 7'	System	21 Sep 2020 18:25:06



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0'	System	27 Sep 2020 20:22:32
User entered 'No interference with activity (1)'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:05', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0'	System	27 Sep 2020 20:22:32
User entered 'No interference with activity (1)'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:12', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0' User entered 'None (0)'	System	27 Sep 2020 20:22:32
	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:17', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0'	System	27 Sep 2020 20:22:32
User entered 'No interference with activity (1)'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:20', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0' User entered 'None (0)'	System	27 Sep 2020 20:22:32
	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:23', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0' User entered 'None (0)'	System	27 Sep 2020 20:22:32
	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:26', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0' User entered 'No (N)'	System	27 Sep 2020 20:22:32
	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-27T13:22:29', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'c1110446-6f66-4f49-b8a6-3f937e1ddbe0' User entered '27 Sep 2020 13:22'	System	27 Sep 2020 20:22:32
	System	27 Sep 2020 20:22:32



US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:25:06

US3112365

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	27 Sep 2020 20:22:32
User entered 'Day 8'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:13:11

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:01', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '5cf472da-eb17-4685-aa0a-bc38d2509e4d' User entered 'None (0)'	System	28 Sep 2020 23:15:11
	System	28 Sep 2020 23:15:11

US3112365

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:07', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '5cf472da-eb17-4685-aa0a-bc38d2509e4d' User entered '28 Sep 2020 16:15'	System	28 Sep 2020 23:15:11
	System	28 Sep 2020 23:15:11

US3112365

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	27 Sep 2020 20:22:32
User entered 'Day 8'	System	27 Sep 2020 20:22:32



US3112365

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:13:11

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:11', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '232cb303-cc8e-4eaa-8fdd-59331f7dfc76' User entered 'None (0)'	System	28 Sep 2020 23:15:22
	System	28 Sep 2020 23:15:22

US3112365

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:17', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '232cb303-cc8e-4eaa-8fdd-59331f7dfc76' User entered '28 Sep 2020 16:15'	System	28 Sep 2020 23:15:22
	System	28 Sep 2020 23:15:22

US3112365

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	27 Sep 2020 20:22:32
User entered 'Day 8'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:13:11

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:21', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a7b6802e-e011-4df2-b83f-26573cf4d558' User entered 'None (0)'	System	28 Sep 2020 23:15:28
	System	28 Sep 2020 23:15:28

US3112365

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:24', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a7b6802e-e011-4df2-b83f-26573cf4d558'	System	28 Sep 2020 23:15:28
User entered '28 Sep 2020 16:15'	System	28 Sep 2020 23:15:28

US3112365

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 20:22:32



US3112365

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
Data entry locked.	System	27 Sep 2020 20:22:32
User entered 'Day 8'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:13:11

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)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:28', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '73d3305a-99c0-4092-9004-8b24c8fb09e8' User entered 'No (N)'	System	28 Sep 2020 23:15:34
	System	28 Sep 2020 23:15:34

US3112365

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-09-28T16:15:30', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '73d3305a-99c0-4092-9004-8b24c8fb09e8' User entered '28 Sep 2020 16:15'	System	28 Sep 2020 23:15:34
	System	28 Sep 2020 23:15:34

US3112365

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 20:22:32

US3112365

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:13:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:06
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 20:22:32

US3112365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	28 Sep 2020 23:22:05
	(b) (4)	

US3112365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered '28 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	28 Sep 2020 23:22:05



US3112365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	28 Sep 2020 23:22:05

US3112365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered empty.	(b) (4) Matthew Musikanth	28 Sep 2020 23:22:05
	(b) (4)	

US3112365

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:56:39
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	28 Sep 2020 23:22:08
	(b) (4)	

US3112365

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	28 Sep 2020 23:22:08

US3112365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:27:52

US3112365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:27:52

US3112365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:27:52

US3112365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:27:52



US3112365

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:27:58

US3112365

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	12 Oct 2020 20:27:58

US3112365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:28:09

US3112365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '12 Oct 2020'	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:28:09

US3112365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:28:09

US3112365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	(b) (4) Natalie Moy (b) (4)	12 Oct 2020 20:28:09

US3112365

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	Natalie Moy (b) (4)	12 Oct 2020 20:28:16

US3112365

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	12 Oct 2020 20:28:16



US3112365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:54:21

US3112365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '19 Oct 2020'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:54:21

US3112365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	19 Oct 2020 22:54:21

US3112365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'VISIT3'	System	19 Oct 2020 22:54:21

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '19 Oct 2020'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '10:15'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '19 Oct 2020 10:15'	System	19 Oct 2020 22:55:05



US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '98.3' F	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '62'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'bpm'	System	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '16'	Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'breaths/min'	System	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '145'	Natalie Moy (b) (4)	19 Oct 2020 22:55:05



US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '83'	Natalie Moy (b) (4)	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'mmHg'	System	19 Oct 2020 22:55:05

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33

US3112365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33

US3112365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'No (N)'	Natalie Moy (b) (4)	19 Oct 2020 22:55:12

US3112365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered empty.	Natalie Moy (b) (4)	19 Oct 2020 22:55:12

US3112365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	Natalie Moy (b) (4)	19 Oct 2020 22:55:26



US3112365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is recorded under Visit3 Day57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 08:39:37
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is recorded under Visit3 Day57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'sample was collected 19oct2020 on visit 3 day 57' (Site from DM).	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 20:16:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is recorded under Visit3 Day57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:51:36
User entered '19 Oct 2020'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 22:55:26

US3112365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered '10:25'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:55:26

US3112365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered '19 Oct 2020 10:25'	System	19 Oct 2020 22:55:26

US3112365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:27:09
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 22:55:30

US3112365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	19 Oct 2020 22:55:30

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 64'	System	24 Aug 2020 23:42:16

US3112365

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56



US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56



US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 23:42:16



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 23:42:16

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 71'	System	24 Aug 2020 23:42:16

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

**US3112365**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56



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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

US3112365

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 23:42:16

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

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**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 23:42:16

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Folder: Safety Follow Up Diary (1)

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**TIMEPOINT**

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered 'Day 78'	System	24 Aug 2020 23:42:16

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

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[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)
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Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56



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Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56



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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 23:42:16



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:07:56
Data entry locked.	System	24 Aug 2020 23:42:16
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 23:42:16

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-11-22T15:47:04', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e1f784d2-bff3-4e3c-a80b-fdf55fce04da'	System	22 Nov 2020 23:47:18
User entered 'No (N)'	System	22 Nov 2020 23:47:18

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-11-22T15:47:08', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e1f784d2-bff3-4e3c-a80b-fdf55fce04da'	System	22 Nov 2020 23:47:18
User entered 'No (N)'	System	22 Nov 2020 23:47:18

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-11-22T15:47:14', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'e1f784d2-bff3-4e3c-a80b-fdf55fce04da' User entered '22 Nov 2020 15:47:14'	System	22 Nov 2020 23:47:18

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:07:56



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 02:07:56



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-12-23T14:30:19', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f8cf8301-1731-4b0f-9e99-a258f6e7b33b' User entered 'No (N)'	System	23 Dec 2020 22:30:35
	System	23 Dec 2020 22:30:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-12-23T14:30:24', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f8cf8301-1731-4b0f-9e99-a258f6e7b33b' User entered 'No (N)'	System	23 Dec 2020 22:30:35
	System	23 Dec 2020 22:30:35

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2020-12-23T14:30:31', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'f8cf8301-1731-4b0f-9e99-a258f6e7b33b' User entered '23 Dec 2020 14:30:31'	System	23 Dec 2020 22:30:35
	System	23 Dec 2020 22:30:35

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 02:07:56



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-01T17:22:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '5856a395-9e86-4eaf-b07d-4aac38a643e0' User entered 'No (N)'	System	02 Jan 2021 01:22:58
	System	02 Jan 2021 01:22:58

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-01T17:22:45', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '5856a395-9e86-4eaf-b07d-4aac38a643e0' User entered 'No (N)'	System	02 Jan 2021 01:22:58
	System	02 Jan 2021 01:22:58

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-01T17:22:55', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '5856a395-9e86-4eaf-b07d-4aac38a643e0' User entered '01 Jan 2021 17:22:55'	System	02 Jan 2021 01:22:58
	System	02 Jan 2021 01:22:58

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:07:56



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-08T09:01:31', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2cc2afb5-540f-4636-b1cf-e910e65ded54' User entered 'No (N)'	System	08 Jan 2021 17:02:26

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-08T09:01:36', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2cc2afb5-540f-4636-b1cf-e910e65ded54' User entered 'No (N)'	System	08 Jan 2021 17:02:26
	System	08 Jan 2021 17:02:26

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-08T09:01:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2cc2afb5-540f-4636-b1cf-e910e65ded54' User entered '08 Jan 2021 09:01:40'	System	08 Jan 2021 17:02:26
	System	08 Jan 2021 17:02:26

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 02:07:56

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-29T19:30:57', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '107b364c-b128-401b-a226-39753a5ef9bd' User entered 'No (N)'	System	30 Jan 2021 03:31:21
	System	30 Jan 2021 03:31:21

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-29T19:31:09', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '107b364c-b128-401b-a226-39753a5ef9bd' User entered 'No (N)'	System	30 Jan 2021 03:31:21
	System	30 Jan 2021 03:31:21

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-01-29T19:31:16', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '107b364c-b128-401b-a226-39753a5ef9bd' User entered '29 Jan 2021 19:31:16'	System	30 Jan 2021 03:31:21

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 02:07:56



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-02-04T11:15:31', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a4240abc-f8d5-4f71-9779-818bb6c90216' User entered 'No (N)'	System	04 Feb 2021 19:15:43

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-02-04T11:15:35', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a4240abc-f8d5-4f71-9779-818bb6c90216' User entered 'No (N)'	System	04 Feb 2021 19:15:43

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-02-04T11:15:40', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'a4240abc-f8d5-4f71-9779-818bb6c90216' User entered '04 Feb 2021 11:15:40'	System	04 Feb 2021 19:15:43
	System	04 Feb 2021 19:15:43

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:07:56



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-02-17T10:48:03', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'cc78966c-2975-4d6e-b1fc-ce9a336e5d0d' User entered 'No (N)'	System	17 Feb 2021 18:48:35
	System	17 Feb 2021 18:48:35

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-02-17T10:48:11', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'cc78966c-2975-4d6e-b1fc-ce9a336e5d0d' User entered 'No (N)'	System	17 Feb 2021 18:48:35

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-02-17T10:48:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'cc78966c-2975-4d6e-b1fc-ce9a336e5d0d' User entered '17 Feb 2021 10:48:25'	System	17 Feb 2021 18:48:35
	System	17 Feb 2021 18:48:35

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:07:56

**US3112365**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-03-24T08:58:15', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'af9cd749-38a7-4230-a232-fd45940c259e' User entered 'No (N)'	System	24 Mar 2021 15:58:57
	System	24 Mar 2021 15:58:57

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-03-24T08:58:19', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'af9cd749-38a7-4230-a232-fd45940c259e' User entered 'Yes (Y)'	System	24 Mar 2021 15:58:57
	System	24 Mar 2021 15:58:57

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-03-24T08:58:35', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'af9cd749-38a7-4230-a232-fd45940c259e'	System	24 Mar 2021 15:58:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Mar 2021 15:58:57



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-03-24T08:58:48', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'af9cd749-38a7-4230-a232-fd45940c259e' User entered '24 Mar 2021 08:58:48'	System	24 Mar 2021 15:58:57
	System	24 Mar 2021 15:58:57

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-01T09:08:25', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ab6c52b1-3ab7-46f7-af05-35577834754d' User entered 'No (N)'	System	01 Apr 2021 16:17:48
	System	01 Apr 2021 16:17:48

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-01T09:08:28', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ab6c52b1-3ab7-46f7-af05-35577834754d' User entered 'No (N)'	System	01 Apr 2021 16:17:48

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-01T09:08:39', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ab6c52b1-3ab7-46f7-af05-35577834754d' User entered '01 Apr 2021 09:08:39'	System	01 Apr 2021 16:17:48
	System	01 Apr 2021 16:17:48

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-07T12:16:59', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '72d05670-49b4-4d52-96a1-6d09ceec0b6f' User entered 'No (N)'	System	07 Apr 2021 19:17:13
	System	07 Apr 2021 19:17:13

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-07T12:17:03', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '72d05670-49b4-4d52-96a1-6d09ceec0b6f' User entered 'No (N)'	System	07 Apr 2021 19:17:13
	System	07 Apr 2021 19:17:13

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-07T12:17:09', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '72d05670-49b4-4d52-96a1-6d09ceec0b6f' User entered '07 Apr 2021 12:17:09'	System	07 Apr 2021 19:17:13
	System	07 Apr 2021 19:17:13

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-14T16:03:32', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '7c1de92c-5d40-4e75-a43b-f83117536c06' User entered 'No (N)'	System	14 Apr 2021 23:04:42
	System	14 Apr 2021 23:04:42

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-14T16:03:41', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '7c1de92c-5d40-4e75-a43b-f83117536c06' User entered 'No (N)'	System	14 Apr 2021 23:04:42

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-14T16:03:45', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '7c1de92c-5d40-4e75-a43b-f83117536c06' User entered '14 Apr 2021 16:03:45'	System	14 Apr 2021 23:04:42
	System	14 Apr 2021 23:04:42

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-23T13:53:48-07:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba9a448d-7f45-4982-8cac-c209f4ccd451'	System	23 Apr 2021 20:54:00
User entered 'No (N)'	System	23 Apr 2021 20:54:00

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-23T13:53:51-07:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba9a448d-7f45-4982-8cac-c209f4ccd451' User entered 'No (N)'	System	23 Apr 2021 20:54:00
	System	23 Apr 2021 20:54:00



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-23T13:53:57-07:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ba9a448d-7f45-4982-8cac-c209f4ccd451'	System	23 Apr 2021 20:54:00
User entered '23 Apr 2021 13:53:57'	System	23 Apr 2021 20:54:00

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-30T05:47:37-07:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d493ed1-07ef-4f94-8642-026531aaf7ad' User entered 'No (N)'	System	30 Apr 2021 12:47:57
	System	30 Apr 2021 12:47:57

US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

Have you been exposed to someone with 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 (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-30T05:47:43-07:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d493ed1-07ef-4f94-8642-026531aaf7ad' User entered 'No (N)'	System	30 Apr 2021 12:47:57
	System	30 Apr 2021 12:47:57

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-04-30T05:47:53-07:00', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: '2d493ed1-07ef-4f94-8642-026531aaf7ad' User entered '30 Apr 2021 05:47:53'	System	30 Apr 2021 12:47:57
	System	30 Apr 2021 12:47:57

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:07:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 02:07:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:07:56



US3112365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 02:07:56



**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 02:07:56

**US3112365**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:13:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:07:56
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 02:07:56

US3112365

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:13:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-03-22T13:35:27', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ea8e51ba-17fa-4104-97a1-efd1de805cd8'	System	22 Mar 2021 20:35:38
User entered 'No (N)'	System	22 Mar 2021 20:35:38

US3112365

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:13:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34804D8A-22B2-4D86-8C38-56BA4A7FFA67)', Time: '2021-03-22T13:35:31', User OID: 'PatientReportedOutcome (US3112365)', ODM File OID: 'ea8e51ba-17fa-4104-97a1-efd1de805cd8' User entered '22 Mar 2021 13:35:31'	System	22 Mar 2021 20:35:38
	System	22 Mar 2021 20:35:38

US3112365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:59:30
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	16 Nov 2020 19:53:05
	(b) (4)	

US3112365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:59:30
User entered '16 Nov 2020'	(b) (4) Matthew Musikanth	16 Nov 2020 19:53:05
	(b) (4)	

US3112365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:59:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	16 Nov 2020 19:53:05



US3112365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:59:30
User entered empty.	(b) (4) Matthew Musikanth	16 Nov 2020 19:53:05
	(b) (4)	

US3112365

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:59:30
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	16 Nov 2020 19:53:09
	(b) (4)	

US3112365

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:47:33
User entered 'I'	System	16 Nov 2020 19:53:09

US3112365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	22 Dec 2020 01:09:57

US3112365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '21 Dec 2020'	Matthew Musikanth (b) (4)	22 Dec 2020 01:09:57

**US3112365**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:13:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	22 Dec 2020 01:09:57

US3112365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Matthew Musikanth (b) (4)	22 Dec 2020 01:09:57

US3112365

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	22 Dec 2020 01:10:04



US3112365

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'I'	System	22 Dec 2020 01:10:04

US3112365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	20 Jan 2021 00:18:29

US3112365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '19 Jan 2021'	Matthew Musikanth (b) (4)	20 Jan 2021 00:18:29

US3112365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	20 Jan 2021 00:18:29

US3112365

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Matthew Musikanth (b) (4)	20 Jan 2021 00:18:29

US3112365

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	20 Jan 2021 00:18:35

US3112365

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'I'	System	20 Jan 2021 00:18:35

US3112365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	18 Feb 2021 21:56:14



US3112365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '18 Feb 2021'	Natalie Moy (b) (4) (b) (4)	18 Feb 2021 21:56:14

US3112365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4) (b) (4)	18 Feb 2021 21:56:14

US3112365

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	18 Feb 2021 21:56:14

US3112365

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	18 Feb 2021 21:56:17

US3112365

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'I'	System	18 Feb 2021 21:56:17

US3112365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:34

US3112365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '22 Mar 2021'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:34

US3112365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:34



US3112365

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'VISIT4'	System	22 Mar 2021 21:53:34

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '22 Mar 2021'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '09:59'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered '22 Mar 2021 09:59'	System	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '98.0' F	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22



US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '59'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

**US3112365**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:13:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'bpm'	System	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '16'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'breaths/min'	System	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '137'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'mmHg'	System	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '80'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 17:16:22

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'mmHg'	System	30 Mar 2021 17:16:22



US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50

US3112365

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50

US3112365

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:46

US3112365

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:46

US3112365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:55

US3112365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '22 Mar 2021'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:55

US3112365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '10:05'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:55

US3112365

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered '22 Mar 2021 10:05'	System	22 Mar 2021 21:53:55



US3112365

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 21:53:58

US3112365

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:17:50
User entered 'I'	System	22 Mar 2021 21:53:58

US3112365

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 18:23:08

US3112365

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:10
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 18:23:08

US3112365

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Apr 2021 18:23:08

US3112365

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:10
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 18:23:08

US3112365

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 18:23:11

**US3112365**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:13:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 18:23:11



US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	04 Jan 2021 22:08:14
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '04 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:08:14
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[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 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	04 Jan 2021 22:08:14
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 22:08:14

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:08:36
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

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 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:51:17

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	04 Jan 2021 22:08:36
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:40:40
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:52:23
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	08 Apr 2021 16:30:18
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	08 Apr 2021 16:29:58
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Apr 2021 16:29:58
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:19:41
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'AMENDMENT 5 (AMENDMENT 5)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:51:17



US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:08:36
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	04 Jan 2021 22:08:36
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:19:04
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	04 Jan 2021 22:08:36
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:19:04
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	04 Jan 2021 22:08:36
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	04 Jan 2021 22:08:36
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '1'	System	04 Jan 2021 22:08:36

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:13:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'I'	System	04 Jan 2021 22:08:36

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '70.5' in	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	



US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '231' lb	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '32.74490'	System	04 Jan 2021 22:10:18
DataPoint set to visible.	System	04 Jan 2021 22:08:36

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '70.5' in	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '231' lb	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '32.74490'	System	04 Jan 2021 22:10:18
DataPoint set to visible.	System	04 Jan 2021 22:08:36

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '11:07'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '4 Jan 2021 11:07'	System	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '98.1' F	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '68'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'bpm'	System	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '14'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'breaths/min'	System	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '124'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	04 Jan 2021 22:10:18

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '75'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '70.5' in	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '231' lb	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '32.74490'	System	04 Jan 2021 22:10:18
DataPoint set to visible.	System	04 Jan 2021 22:08:36



US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:10:18

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:10:18

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '12:05'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '4 Jan 2021 12:05'	System	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '98.9' F	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:10:18



US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '78'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'bpm'	System	04 Jan 2021 22:10:18

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '16'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'breaths/min'	System	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '128'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	04 Jan 2021 22:10:18

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '82'	Natalie Moy (b) (4)	04 Jan 2021 22:10:18
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	04 Jan 2021 22:10:18



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:10:25

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:10:25
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	04 Jan 2021 22:11:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	04 Jan 2021 22:11:01
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

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 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	04 Jan 2021 22:11:01
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mRNA-1273'	System	04 Jan 2021 22:11:01
DataPoint set to visible.	System	04 Jan 2021 22:08:36

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:11:01
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '11:34'	Natalie Moy (b) (4)	04 Jan 2021 22:11:01
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '4 Jan 2021 11:34'	System	04 Jan 2021 22:11:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4)	04 Jan 2021 22:11:01
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'ONCE'	System	04 Jan 2021 22:11:01

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'INTRAMUSCULAR'	System	04 Jan 2021 22:11:01

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	04 Jan 2021 22:11:19
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:11:19
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '11:21'	Natalie Moy (b) (4)	04 Jan 2021 22:11:19
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '4 Jan 2021 11:21'	System	04 Jan 2021 22:11:19



US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Jan 2021 22:11:26

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:13:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '4 Jan 2021'	Natalie Moy (b) (4)	04 Jan 2021 22:11:26
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '11:12'	Natalie Moy (b) (4)	04 Jan 2021 22:11:26
	(b) (4)	

US3112365

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:13:11**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '4 Jan 2021 11:12'	System	04 Jan 2021 22:11:26

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	04 Jan 2021 22:11:28
	(b) (4)	

US3112365

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'I'	System	04 Jan 2021 22:11:28

US3112365

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	11 Jan 2021 21:28:48
	(b) (4)	

US3112365

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '11 Jan 2021'	Karen Mylerberg (b) (4)	11 Jan 2021 21:28:48
	(b) (4)	



US3112365

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	11 Jan 2021 21:28:48
	(b) (4)	

US3112365

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	11 Jan 2021 21:28:48
	(b) (4)	

US3112365

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	11 Jan 2021 21:28:39
	(b) (4)	

**US3112365**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:13:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'I'	System	11 Jan 2021 21:28:39

US3112365

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '1'	System	11 Jan 2021 21:28:39
DataPoint set to visible.	System	11 Jan 2021 21:28:39

US3112365

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:36:22
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '29 Jan 2021'	Karen Mylerberg (b) (4)	08 Feb 2021 23:36:22
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

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 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:36:22
	(b) (4)	



**US3112365**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:13:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'OLD29'	System	08 Feb 2021 23:36:22

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '29 Jan 2021'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '10:59'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '29 Jan 2021 10:59'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '98.4' F	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27



US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '72'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

**US3112365**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'bpm'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'breaths/min'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '115'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '083'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27



**US3112365**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '29 Jan 2021'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '12:10'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '29 Jan 2021 12:10'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '98.9' F	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27



US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '76'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'bpm'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'breaths/min'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '130'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:27
	(b) (4)	

**US3112365**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '080'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:37:27



US3112365

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	08 Feb 2021 23:37:27

US3112365

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:41
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '29 Jan 2021'	Karen Mylerberg (b) (4)	08 Feb 2021 23:37:41
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:38:11

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:11
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

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 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:11
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mRNA-1273'	System	08 Feb 2021 23:38:11
DataPoint set to visible.	System	11 Jan 2021 21:28:39

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '29 Jan 2021'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:11
	(b) (4)	



US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '11:39'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:11
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '29 Jan 2021 11:39'	System	08 Feb 2021 23:38:11

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:11
	(b) (4)	

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'ONCE'	System	08 Feb 2021 23:38:11

US3112365

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 23:38:11

US3112365

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:17
	(b) (4)	

**US3112365**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:13:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'I'	System	08 Feb 2021 23:38:17

US3112365

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:31
	(b) (4)	



US3112365

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '8 Feb 2021'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:31
	(b) (4)	

US3112365

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:31
	(b) (4)	

US3112365

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:31
	(b) (4)	

US3112365

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	08 Feb 2021 23:38:40
	(b) (4)	

US3112365

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'I'	System	08 Feb 2021 23:38:40

US3112365

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Mar 2021 00:24:59

US3112365

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '3 Mar 2021'	Natalie Moy (b) (4)	04 Mar 2021 00:24:59
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:11

[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 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	04 Mar 2021 00:24:59
	(b) (4)	



**US3112365**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:13:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'OLD57'	System	04 Mar 2021 00:24:59

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Mar 2021 00:25:41

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '3 Mar 2021'	Natalie Moy (b) (4)	04 Mar 2021 00:25:41
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '10:13'	Natalie Moy (b) (4)	04 Mar 2021 00:25:41
	(b) (4)	

**US3112365**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:13:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '3 Mar 2021 10:13'	System	04 Mar 2021 00:25:41

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '98.3' F	Natalie Moy (b) (4)	04 Mar 2021 00:25:41
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	04 Mar 2021 00:25:41

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Mar 2021 00:25:41



US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '65'	Natalie Moy (b) (4)	04 Mar 2021 00:25:41
	(b) (4)	

**US3112365**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:13:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'bpm'	System	04 Mar 2021 00:25:41

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '10'	Natalie Moy (b) (4)	04 Mar 2021 00:25:41
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'breaths/min'	System	04 Mar 2021 00:25:41

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '143'	Natalie Moy (b) (4)	04 Mar 2021 00:25:41
	(b) (4)	

**US3112365**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:13:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	04 Mar 2021 00:25:41

US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '77'	Natalie Moy (b) (4)	04 Mar 2021 00:25:41
	(b) (4)	

**US3112365**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:13:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered 'mmHg'	System	04 Mar 2021 00:25:41



US3112365

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04

**US3112365**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:13:11**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04

US3112365

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Natalie Moy (b) (4)	04 Mar 2021 00:25:46
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	04 Mar 2021 00:25:46
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	04 Mar 2021 00:25:54
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '3 Mar 2021'	Natalie Moy (b) (4)	04 Mar 2021 00:25:54
	(b) (4)	

US3112365

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '10:23'	Natalie Moy (b) (4)	04 Mar 2021 00:25:54
	(b) (4)	

**US3112365**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:13:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:12:04
User entered '3 Mar 2021 10:23'	System	04 Mar 2021 00:25:54



US3112365

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:13:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:45:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:47
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:41:21

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:11:12
User entered 'USA-US062-2020-mRNA-1273-P301000008'	System	17 Nov 2020 15:10:54
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 15:10:54

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Thoracic vertebral fracture, LLT: Thoracic vertebral fracture T12 - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 07:03:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 07:03:54
DataPoint Verified.	(b) (4)	20 Nov 2020 01:00:04
	(b) (4), (b) (6)	
Data point term sent to Coder	System	20 Nov 2020 00:38:29
User closed query 'For coding purposes, please split C11 FRACTURE SECONDARY TO MECHANICAL FALL into separate entries. 1. C11 FRACTURE [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' (Site from System).	System	20 Nov 2020 00:38:26
Query 'For coding purposes, please split C11 FRACTURE SECONDARY TO MECHANICAL FALL into separate entries. 1. C11 FRACTURE [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' answered with 'updated' (Site from System).	Matthew Musikanth (b) (4)	20 Nov 2020 00:38:26
Data point term sent to Coder	System	20 Nov 2020 00:30:11
User entered 'T12 FRACTURE' reason for change:	Matthew Musikanth	20 Nov 2020 00:29:54
Data Entry Error	(b) (4)	
User opened query 'For coding purposes, please split C11 FRACTURE SECONDARY TO MECHANICAL FALL into separate entries. 1. C11 FRACTURE [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' (Site from System).	Coder Import (b) (4)	16 Nov 2020 19:54:46
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 19:45:03
User entered 'C11 Fracture secondary to mechanical fall'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered empty.	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46



**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:13:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:44:46

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
	(b) (4), (b) (6)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 02:33:25
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'SAE event has ended per surgery date, however patient is post-op recovering. ' (Site from System).	Matthew Musikanth (b) (4)	16 Nov 2020 19:45:28
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Nov 2020 19:44:46
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered empty.	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:13:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:44:46

US3112365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '0'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46



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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '0'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'I'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '06 Nov 2020'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered empty.	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '0'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '0'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46



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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '0'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered '0'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'I'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 20:26:56
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'conproc listed a reconstruction on the same day' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 21:20:20
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 00:15:26
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'I'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:24:17
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AE has resolved ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	14 Dec 2020 19:51:59
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	14 Dec 2020 19:51:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Brenda Grande (b) (4) (b) (4)	14 Dec 2020 19:51:43
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:56:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46



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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04
User entered empty.	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:43:43
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User closed query 'Per DM CLR: SAE Narrative = WAS OPERATED ON THAT DAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 20:26:59
User closed query 'Per DM CLR: SAE Narrative = MECHANICAL FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 20:26:58
Query 'Per DM CLR: SAE Narrative = WAS OPERATED ON THAT DAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'per conproc eCRF, pt had a reconstruction done on 2nd of November' (Site from DM).	Natalie Moy (b) (4)	28 Jan 2021 21:20:58
	(b) (4)	
Query 'Per DM CLR: SAE Narrative = MECHANICAL FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'previously listed mechanical fall, the fracture is the AE' (Site from DM).	Natalie Moy (b) (4)	28 Jan 2021 21:20:38
	(b) (4)	
User opened query 'Per DM CLR: SAE Narrative = WAS OPERATED ON THAT DAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 00:15:19
User opened query 'Per DM CLR: SAE Narrative = MECHANICAL FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 00:15:07

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify whether there was metastasis of prostatic cancer at T12 or whether there was marked degenerative change at T12.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 17:06:37
Query 'PV Query: Please clarify whether there was metastasis of prostatic cancer at T12 or whether there was marked degenerative change at T12.' answered with 'neither, fracture due to mechanical fall. ' (Site from Safety).	Matthew Musikanth (b) (4)	29 Dec 2020 00:44:31
User opened query 'PV Query: Please clarify whether there was metastasis of prostatic cancer at T12 or whether there was marked degenerative change at T12.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 14:20:14
User closed query 'PV Query: Since the subject had T12 fracture, not C11 fracture, please update case narrative in the SD accordingly.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:47:10
Query 'PV Query: Since the subject had T12 fracture, not C11 fracture, please update case narrative in the SD accordingly.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	18 Dec 2020 19:15:21
User entered 'PT EXPERIENCED MECHANICAL FALL FROM A LADDER, FRACTURING VERTEBRAE T12. PATIENT DENIED HOSPITAL VISIT UNTIL 02NOV2020 WHEN PATIENT EXPERIENCED HEMATURIA. PATIENT THEN RECIEVED DIAGNOSIS OF FRACTURE AND WAS OPERATED ON THAT DAY. PT REMAINED IN PATIENT AT SCRIPPS ENCINITAS FOR MONITORING POST-OP UNTIL 06NOV2020. NOTE: THE EVENT TERM T12 FRACTURE IS AN UPDATED TERM OF T12 FRACTURE SECONDARY TO MECHANICAL FALL PER QUERY RESOLUTION' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Dec 2020 19:15:15
User opened query 'PV Query: Since the subject had T12 fracture, not C11 fracture, please update case narrative in the SD accordingly.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 17:54:23
User closed query 'PV Query: If the fall was not accidental, please clarify whether the fall meets criteria of SAE or AE.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:24:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:24:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:24:26
User closed query 'PV Query:#1. Please confirm whether the fall was accidental. Was the subject conscious during the fall?' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:24:24
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) (6)	15 Dec 2020 19:24:20
Query 'PV Query: If the fall was not accidental, please clarify whether the fall meets criteria of SAE or AE.' answered with 'The fall was accidental ' (Site from Safety).	Brenda Grande (b) (4)	14 Dec 2020 20:10:16
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'subject remained hospitalized for observation ' (Site from Safety).	Brenda Grande (b) (4)	14 Dec 2020 20:10:03
Query 'PV Query:#1. Please confirm whether the fall was accidental. Was the subject conscious during the fall?' answered with 'The fall was accidental and the subject was conscious the entire time ' (Site from Safety).	Brenda Grande (b) (4)	14 Dec 2020 20:06:49
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'relevant laboratory and diagnostic tests have been added to Concomitant Procedures' (Site from Safety).	Brenda Grande (b) (4)	14 Dec 2020 20:06:24
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 'rapid covid-19 test performed results came back negative ' (Site from Safety).	Brenda Grande (b) (4)	14 Dec 2020 20:03:26

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: If the fall was not accidental, please clarify whether the fall meets criteria of SAE or AE.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:01:26
Query '#2. If the fall was not accidental, please clarify whether the fall meets criteria of SAE or AE.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:01:15
User opened query '#2. If the fall was not accidental, please clarify whether the fall meets criteria of SAE or AE.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:01:12
Query '#2. If the fall was not accidental, please clarify whether the fall meets criteria of SAE or AE.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:01:08
User opened query '#2. If the fall was not accidental, please clarify whether the fall meets criteria of SAE or AE.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:01:02
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:00:48
User closed query 'PV Query: Please confirm if the event term of 'T12 fracture' is an updated term of 'C11 fracture secondary to mechanical fall.' If so, please clarify in the case narrative.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:06:41
Query 'PV Query: Please confirm if the event term of 'T12 fracture' is an updated term of 'C11 fracture secondary to mechanical fall.' If so, please clarify in the case narrative.' answered with 'updated' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	03 Dec 2020 21:45:26
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	03 Dec 2020 21:45:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT EXPERIENCED MECHANICAL FALL FROM A LADDER, FRACTURING VERTEBRAE C11. PATIENT DENIED HOSPITAL VISIT UNTIL 02NOV2020 WHEN PATIENT EXPERIENCED HEMATURIA. PATIENT THEN RECIEVED DIAGNOSIS OF FRACTURE AND WAS OPERATED ON THAT DAY. PT REMAINED IN PATIENT AT SCRIPPS ENCINITAS FOR MONITORING POST-OP UNTIL 06NOV2020. note: the event term t12 fracture is an updated term of c11 fracture secondary to mechanical fall per query resolution' reason for change: Data Entry Error	Natalie Moy (b) (4)	03 Dec 2020 21:45:19
User opened query 'PV Query:#1. Please confirm whether the fall was accidental. Was the subject conscious during the fall?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:57:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:56:59
User opened query 'PV Query: Please confirm if the event term of 'T12 fracture' is an updated term of 'C11 fracture secondary to mechanical fall.' If so, please clarify in the case narrative.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:56:48
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)	25 Nov 2020 11:56:33
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:04

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT EXPERIENCED MECHANICAL FALL FROM A LADDER, FRACTURING VERTEBRAE C11. PATIENT DENIED HOSPITAL VISIT UNTIL 02NOV2020 WHEN PATIENT EXPERIENCED HEMATURIA. PATIENT THEN RECIEVED DIAGNOSIS OF FRACTURE AND WAS OPERATED ON THAT DAY. PT REMAINED IN PATIENT AT SCRIPPS ENCINITAS FOR MONITORING POST-OP UNTIL 06NOV2020.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	20 Nov 2020 00:29:54
User entered 'Pt experienced mechanical fall from a ladder, fracturing vertebrae c11. Patient denied hospital visit until 02Nov2020 when patient experienced hematuria. Patient then recieved diagnosis of fracture and was operated on that day. Pt remained in patient at Scripps Encinitas for monitoring post-op until 06Nov2020. Pending medical records for additional information.'	Matthew Musikanth (b) (4)	16 Nov 2020 19:44:46

**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:44:46



**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 19:44:46

**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 19:44:46

US3112365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02

US3112365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 10:33:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 10:33:14
Data point term sent to Coder	System	29 Dec 2020 00:44:19
Coding entries removed.	Matthew Musikanth (b) (4)	29 Dec 2020 00:43:45
User entered 'Cellulitis Lower Left Extremity' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Dec 2020 00:43:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Wound infection, LLT: Wound infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 15:32:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 15:32:46
Data point term sent to Coder	System	22 Dec 2020 01:12:17
User entered 'Infected wound'	Matthew Musikanth (b) (4)	22 Dec 2020 01:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

US3112365

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '27 Nov 2020' reason for change: New Information	Matthew Musikanth (b) (4)	23 Dec 2020 23:48:19
User entered '26 Nov 2020'	Matthew Musikanth (b) (4)	22 Dec 2020 01:12:08



**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User entered empty.	System	22 Dec 2020 01:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	11 Jan 2021 21:30:22
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '06 Dec 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	11 Jan 2021 21:30:22
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:13:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

**US3112365**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:13:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User entered empty.	System	22 Dec 2020 01:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '0'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '0'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '0'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '0'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '0'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '0'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered '0'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'I'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:33:03
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'form updated' (Site from DM).	(b) (4), (b) (6) Karen Mylerberg (b) (4) (b) (4)	14 Jan 2021 15:04:32 11 Jan 2021 21:38:56
User entered '0' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	11 Jan 2021 21:30:22
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6) Matthew Musikanth (b) (4)	08 Jan 2021 00:15:53 23 Dec 2020 23:48:25
User entered '0'	Matthew Musikanth (b) (4)	22 Dec 2020 01:12:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	11 Jan 2021 21:30:22
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:33:03
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User entered '0'	System	22 Dec 2020 01:12:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02
User entered '1'	System	22 Dec 2020 01:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:02

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:13:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:45:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:00:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:24:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:01:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:01:55
Data point term sent to Coder Coding entries removed.	System Karen Mylerberg (b) (4) (b) (4)	08 Sep 2020 21:01:20 08 Sep 2020 21:01:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:26:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:26:38
Data point term sent to Coder User entered 'Losartan'	System (b) (4), (b) (6)	25 Aug 2020 19:25:31 25 Aug 2020 19:24:57



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:24:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Hypertension' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	08 Sep 2020 21:01:01
User entered 'HTN'	(b) (4), (b) (6)	25 Aug 2020 19:24:57

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '100'	(b) (4), (b) (6)	25 Aug 2020 19:24:57

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 19:24:57

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 19:24:57



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'UN UNK 2015'	(b) (4), (b) (6)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:24:57

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:24:57

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:24:57



**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 19:24:57

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:27:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:27:41
Data point term sent to Coder	System	25 Aug 2020 19:26:33
User entered 'Pravastatin'	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Hypercholesterolemia'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '80'	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Aug 2020 19:26:08



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'UN UNK 2015'	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:26:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:26:08



**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:26:08

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:26:08

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 19:26:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:28:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:28:36
Data point term sent to Coder	System	25 Aug 2020 19:27:36
User entered 'Omeprazole'	(b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Acid Reflux'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '20'	(b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 19:26:41



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'UN UNK 2018'	(b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:26:41



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:26:41

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:26:41

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 19:26:41

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:28:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:28:37
Data point term sent to Coder	System	25 Aug 2020 19:27:40
User entered 'Qvar'	(b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Asthma'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'puff (PUFF)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'UN UNK 2016'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:27:29

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:27:29

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:27:29

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:27:29

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR [SALBUTAMOL SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:29:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:29:29
Data point term sent to Coder	System	25 Aug 2020 19:28:41
User entered 'Pro Air'	(b) (4), (b) (6)	25 Aug 2020 19:28:19



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Asthma'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '1-2'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'puff (PUFF)'	(b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'UN UNK 2016'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 19:28:19

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:28:19

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:28:19



**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:28:19

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:31:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:31:21
Data point term sent to Coder	System	12 Oct 2020 20:30:04
User entered 'flu vaccine'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'influenza virus prophylaxis'	Natalie Moy (b) (4)	12 Oct 2020 20:29:31
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0.5'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mL (mL)'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'once (ONCE)'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'Intramuscular (INTRAMUSCULAR)'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:29:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 20:29:36
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:36
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:29:31
User entered empty.	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 20:29:31



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User entered empty.	System	12 Oct 2020 20:29:31

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User entered empty.	System	12 Oct 2020 20:29:31

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:40
User entered empty.	System	12 Oct 2020 20:29:31

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:38:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:38:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
Data point term sent to Coder	System	20 Nov 2020 00:39:31
User entered 'morphine'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered 'T12 Fracture'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered '4'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered '0'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:39:16

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User entered empty.	System	20 Nov 2020 00:39:16

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User entered empty.	System	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:47
User entered empty.	System	20 Nov 2020 00:39:16

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:42:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:42:56
Data point term sent to Coder	System	20 Nov 2020 00:41:33
User entered 'dilaudid'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered 'T12 fracture'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 1 mg, etc) instead of instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:27:48
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 1 mg, etc) instead of instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:32:32
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:31:58
User entered '1' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:31:58
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 1 mg, etc) instead of instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:45:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered '1/1'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:47
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:31:58
User entered 'mg (mg)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:31:58
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:03:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:31:58
User closed query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:46:21
Query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field. Update as appropriate. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	01 Dec 2020 20:18:17
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	01 Dec 2020 20:18:09
User entered 'MG/ML' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	01 Dec 2020 20:18:09
User opened query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 08:38:51
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered '1mg/1ml'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered '0'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:13
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:01

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User entered empty.	System	20 Nov 2020 00:41:01

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User entered empty.	System	20 Nov 2020 00:41:01

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:52
User entered empty.	System	20 Nov 2020 00:41:01

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:21:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:21:59
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
Data point term sent to Coder	System	20 Nov 2020 01:02:43
Data point term sent to Coder	System	20 Nov 2020 00:42:34
User entered 'zofran'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered 'T12 Fracture' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	20 Nov 2020 01:01:54
User entered 'T12'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered '4'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered '0'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:50
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:41:35

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User entered empty.	System	20 Nov 2020 00:41:35

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User entered empty.	System	20 Nov 2020 00:41:35



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:10
User entered empty.	System	20 Nov 2020 00:41:35

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:43:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:43:55
Data point term sent to Coder	System	20 Nov 2020 00:42:34
User entered 'TDAP'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered 'Prophylaxis'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered '.5'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered 'Intramuscular (INTRAMUSCULAR)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered '0'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:03:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:42:26



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User entered empty.	System	20 Nov 2020 00:42:26

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User entered empty.	System	20 Nov 2020 00:42:26

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:14
User entered empty.	System	20 Nov 2020 00:42:26

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:48:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:37:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:37:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
Data point term sent to Coder	System	20 Nov 2020 00:44:35
User entered 'NaCl 9%'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered 'T12 Fracture'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered '1000'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered '0'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:03
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:44:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User entered empty.	System	20 Nov 2020 00:44:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User entered empty.	System	20 Nov 2020 00:44:08

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:58
User entered empty.	System	20 Nov 2020 00:44:08

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:45:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:45:57
Data point term sent to Coder	System	20 Nov 2020 00:45:36
User entered 'Omnipaque'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'T12 Fracture'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered '350/100'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'mg/ml'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered '0'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:45:06

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User entered empty.	System	20 Nov 2020 00:45:06

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User entered empty.	System	20 Nov 2020 00:45:06

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:02:02
User entered empty.	System	20 Nov 2020 00:45:06

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 01:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 01:16:41
Data point term sent to Coder Coding entries removed.	System Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:44:29 02 Feb 2021 16:44:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 11:51:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 11:51:43
Data point term sent to Coder User entered 'Keflex'	System Matthew Musikanth (b) (4)	22 Dec 2020 01:13:18 22 Dec 2020 01:13:07



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	22 Dec 2020 01:13:07

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:28:12
Query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:44:28
User entered 'cellulitis LLE' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:44:22
User opened query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:46:18
User entered 'Infected wound'	Matthew Musikanth (b) (4)	22 Dec 2020 01:13:07

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '500'	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	22 Dec 2020 01:13:07

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'three times daily (TID)'	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Oral (ORAL)'	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '28 Nov 2020' reason for change: New Information	Matthew Musikanth (b) (4)	23 Dec 2020 23:49:54
User entered '26 Nov 2020'	Matthew Musikanth (b) (4)	22 Dec 2020 01:13:07

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	Matthew Musikanth (b) (4)	22 Dec 2020 01:13:07

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '06 Dec 2020'	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	22 Dec 2020 01:13:07
	(b) (4)	

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User entered '3'	System	22 Dec 2020 01:13:07

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User entered '1'	System	22 Dec 2020 01:13:07



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:03
User entered '804 (804)'	System	22 Dec 2020 01:13:07

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 12:35:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 12:35:45
Data point term sent to Coder	System	02 Feb 2021 16:45:30
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:45:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 23:52:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 23:52:18
Data point term sent to Coder	System	23 Dec 2020 23:50:44
User entered 'Vancomycin'	Matthew Musikanth (b) (4)	23 Dec 2020 23:50:37

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:28:25
User entered 'cellulitis LLE' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:45:08
Query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:44:53
User opened query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:47:43
User entered 'Infected Wound'	Matthew Musikanth (b) (4)	23 Dec 2020 23:50:37

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '2'	Matthew Musikanth (b) (4)	23 Dec 2020 23:50:37

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'g (g)'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'once (ONCE)'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '27 Nov 2020'	Matthew Musikanth (b) (4)	23 Dec 2020 23:50:37

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '0'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	23 Dec 2020 23:50:37
	(b) (4)	



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User entered empty.	System	23 Dec 2020 23:50:37

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User entered empty.	System	23 Dec 2020 23:50:37

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:23
User entered empty.	System	23 Dec 2020 23:50:37

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
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)	02 Feb 2021 17:02:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 17:02:29
Data point term sent to Coder	System	02 Feb 2021 16:46:31
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:45:34
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)	24 Dec 2020 00:10:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 00:10:18
Data point term sent to Coder	System	24 Dec 2020 00:09:46
User entered 'Tylenol'	Matthew Musikanth (b) (4)	24 Dec 2020 00:09:27

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:28:43
Query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:45:39
User entered 'Cellulitis LLE' reason for change: New Information	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:45:34
User opened query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:47:53
User entered 'Infected wound'	Matthew Musikanth (b) (4)	24 Dec 2020 00:09:27

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '1000'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	24 Dec 2020 00:09:27



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'once (ONCE)'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Oral (ORAL)'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	Matthew Musikanth (b) (4)	24 Dec 2020 00:09:27

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:09:27
	(b) (4)	

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User entered empty.	System	24 Dec 2020 00:09:27

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User entered empty.	System	24 Dec 2020 00:09:27

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:32
User entered empty.	System	24 Dec 2020 00:09:27

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 09:07:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 09:07:42
Data point term sent to Coder Coding entries removed.	System Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:46:31 02 Feb 2021 16:46:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:45:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:45:20
Data point term sent to Coder User entered 'Motrin'	System Matthew Musikanth (b) (4)	24 Dec 2020 00:12:47 24 Dec 2020 00:12:05

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:29:03
Query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:46:10
User entered 'Cellulitis LLE' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:46:03
User opened query 'Per DM CLR: Please update the indication to reflect the location of INFECTED WOUND. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:46:38
User entered 'Infected Wound'	Matthew Musikanth (b) (4)	24 Dec 2020 00:12:05



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '800'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	24 Dec 2020 00:12:05

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'once (ONCE)'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Oral (ORAL)'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '0'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:12:05
	(b) (4)	

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User entered empty.	System	24 Dec 2020 00:12:05

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User entered empty.	System	24 Dec 2020 00:12:05

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:29
User entered empty.	System	24 Dec 2020 00:12:05

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:08:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:08:24
Data point term sent to Coder Coding entries removed.	System Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:47:32 02 Feb 2021 16:46:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:49:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:49:20
Data point term sent to Coder	System	24 Dec 2020 00:12:47
User entered 'Rocephin'	Matthew Musikanth (b) (4)	24 Dec 2020 00:12:47



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Please specify the location of INFECTED WOUND. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:29:24
Query 'Per DM CLR: Please specify the location of INFECTED WOUND. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:46:54
User entered 'Cellulitis LLE' reason for change: New Information	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:46:49
User opened query 'Per DM CLR: Please specify the location of INFECTED WOUND. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:47:05
User entered 'Infected wound'	Matthew Musikanth (b) (4)	24 Dec 2020 00:12:47

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'I'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'g (g)'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'once (ONCE)'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '0'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

**US3112365**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:13:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:12:47
	(b) (4)	

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User entered empty.	System	24 Dec 2020 00:12:47

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User entered empty.	System	24 Dec 2020 00:12:47



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:11
User entered empty.	System	24 Dec 2020 00:12:47

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 16:48:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 16:48:29
Data point term sent to Coder Coding entries removed.	System Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:47:33 02 Feb 2021 16:47:18
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 00:14:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 00:14:18
Data point term sent to Coder User entered 'Omnipaque'	System Matthew Musikanth (b) (4)	24 Dec 2020 00:13:48 24 Dec 2020 00:13:30

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Please specify the location of INFECTED WOUND. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:29:41
Query 'Per DM CLR: Please specify the location of INFECTED WOUND. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:47:24
User entered 'Cellulitis LLE' reason for change: New Information	Brenda Grande (b) (4) (b) (4)	02 Feb 2021 16:47:18
User opened query 'Per DM CLR: Please specify the location of INFECTED WOUND. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:47:17
User entered 'Infected Wound'	Matthew Musikanth (b) (4)	24 Dec 2020 00:13:30

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '350'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	24 Dec 2020 00:13:30

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'once (ONCE)'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	



US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '0'	Matthew Musikanth (b) (4)	24 Dec 2020 00:13:30

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	

US3112365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:13:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	24 Dec 2020 00:13:30
	(b) (4)	



US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:13:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User entered empty.	System	24 Dec 2020 00:13:30

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User entered empty.	System	24 Dec 2020 00:13:30

US3112365

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:13:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:01:16
User entered empty.	System	24 Dec 2020 00:13:30

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:13:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:45:03
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:51:37

US3112365

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:13:11**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:51:57

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:13:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'Ct abdomen with contrast'	Matthew Musikanth (b) (4)	20 Nov 2020 00:51:57

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:51:57

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:13:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:51:57



US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:13:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:25
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:19

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:13:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:25
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'CT 2D reconstruction'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:19

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:25
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:19

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:13:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:25
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:19

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:13:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:34

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:13:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'Chest xray'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:34

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:34

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:13:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:34



US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:13:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:55

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:13:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'Thoracic MRI without contrast'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:55

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:55

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:13:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 01:04:57
User entered empty.	Matthew Musikanth (b) (4)	20 Nov 2020 00:52:55

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:13:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	23 Dec 2020 23:49:02
	(b) (4)	

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:13:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'COVID-19 RAPID test'	Matthew Musikanth	23 Dec 2020 23:49:02
	(b) (4)	

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:58:03
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Subject received covid-19 rapid test due to cellulitis of LLE which corresponds with AE#2 ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 17:40:00
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:58:08
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	23 Dec 2020 23:49:02

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:13:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	23 Dec 2020 23:49:02
	(b) (4)	



US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:13:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '27 Nov 2020'	Matthew Musikanth	23 Dec 2020 23:49:22
	(b) (4)	

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:13:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered 'ECG'	Matthew Musikanth (b) (4)	23 Dec 2020 23:49:22

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:09:31
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'subject got an ECG due to cellulitis of LLE which corresponds with AE#2 ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 17:41:25
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:58:31
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	23 Dec 2020 23:49:22

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:13:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered empty.	Matthew Musikanth	23 Dec 2020 23:49:22
	(b) (4)	

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:13:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:45
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	16 Apr 2021 18:35:29

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:13:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:45
User entered 'COVID-19 Rapid Test'	Matthew Musikanth (b) (4)	16 Apr 2021 18:35:29

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:13:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:45
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	16 Apr 2021 18:35:29

US3112365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:13:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:14:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:05:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:45
User entered empty.	Matthew Musikanth (b) (4)	16 Apr 2021 18:35:29



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'USA-US062-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Laurie'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Han-Conrad'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '9040 Friars Rd St 540'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'San Diego'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'CA'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '92108'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'US'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 15:47:41
User entered '5'	System	15 Dec 2020 19:03:23
User entered '4'	System	14 Dec 2020 21:18:11
User entered '3'	System	04 Dec 2020 14:06:57
User entered '2'	System	20 Nov 2020 16:24:07
User entered '1'	System	17 Nov 2020 15:13:19



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'USA-US062-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Laurie'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Han-Conrad'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '9040 Friars Rd St 540'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'San Diego'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'CA'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '92108'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'US'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 15:47:41
User entered '5'	System	15 Dec 2020 19:03:23
User entered '4'	System	14 Dec 2020 21:18:11
User entered '3'	System	04 Dec 2020 14:06:57
User entered '2'	System	20 Nov 2020 16:24:07
User entered '1'	System	17 Nov 2020 15:13:19



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:13:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered '17/Nov/2020 15:13'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:13:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'USA-US062-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Laurie'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Han-Conrad'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '9040 Friars Rd St 540'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'San Diego'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'CA'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '92108'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'US'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 15:47:41
User entered '5'	System	15 Dec 2020 19:03:23
User entered '4'	System	14 Dec 2020 21:18:11
User entered '3'	System	04 Dec 2020 14:06:57
User entered '2'	System	20 Nov 2020 16:24:07
User entered '1'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:13:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '20/Nov/2020 11:24'	System	20 Nov 2020 16:24:07

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:13:11

**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)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 16:24:07

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'USA-US062-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Laurie'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Han-Conrad'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '9040 Friars Rd St 540'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'San Diego'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'CA'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '92108'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'US'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 15:47:41
User entered '5'	System	15 Dec 2020 19:03:23
User entered '4'	System	14 Dec 2020 21:18:11
User entered '3'	System	04 Dec 2020 14:06:57
User entered '2'	System	20 Nov 2020 16:24:07
User entered '1'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:13:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '04/Dec/2020 09:06'	System	04 Dec 2020 14:06:57

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:13:11

**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)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 21:18:05
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 14:06:57

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'USA-US062-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Laurie'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Han-Conrad'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '9040 Friars Rd St 540'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'San Diego'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'CA'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '92108'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'US'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 15:47:41
User entered '5'	System	15 Dec 2020 19:03:23
User entered '4'	System	14 Dec 2020 21:18:11
User entered '3'	System	04 Dec 2020 14:06:57
User entered '2'	System	20 Nov 2020 16:24:07
User entered '1'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:13:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '14/Dec/2020 16:18'	System	14 Dec 2020 21:18:11

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:13:11

**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)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:02:59
User entered 'I'	(b) (4), (b) (6)	14 Dec 2020 21:18:11



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'USA-US062-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Laurie'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Han-Conrad'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '9040 Friars Rd St 540'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'San Diego'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'CA'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '92108'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'US'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 15:47:41
User entered '5'	System	15 Dec 2020 19:03:23
User entered '4'	System	14 Dec 2020 21:18:11
User entered '3'	System	04 Dec 2020 14:06:57
User entered '2'	System	20 Nov 2020 16:24:07
User entered '1'	System	17 Nov 2020 15:13:19



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:13:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '15/Dec/2020 14:03'	System	15 Dec 2020 19:03:23

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:13:11

**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)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 19:03:23
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 19:03:14

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'USA-US062-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Yes (Y)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'No (N)'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Laurie'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'Han-Conrad'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '9040 Friars Rd St 540'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'San Diego'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered 'CA'	System	17 Nov 2020 15:10:54

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:13:11
User entered '92108'	System	17 Nov 2020 15:10:54



US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:57:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 00:58:44
User entered 'US'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 15:47:41
User entered '5'	System	15 Dec 2020 19:03:23
User entered '4'	System	14 Dec 2020 21:18:11
User entered '3'	System	04 Dec 2020 14:06:57
User entered '2'	System	20 Nov 2020 16:24:07
User entered '1'	System	17 Nov 2020 15:13:19

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:13:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered '21/Dec/2020 09:47'	System	21 Dec 2020 15:47:41

US3112365

Folder: SAE USA-US062-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:13:11

**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)	16 Apr 2021 17:23:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:57:18
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 15:47:41