

US3642268 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:58:27

All time stamps listed in this document are displayed in GMT

US3642268

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

---

Participant ID

US3642268

---

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

---

---

US3642268

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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	SCRN

US3642268

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Date of Birth (MMM yyyy)	(b) (6) 1982
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3642268

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3642268

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3642268

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3642268

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Condition	WRIST SURGERY
Start date (dd MMM yyyy)	18 OCT 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	18 OCT 2018
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	OCT 2018
Stop Year (derived)	2018



US3642268

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

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

US3642268

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Condition	PROSTATITIS
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3642268

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Condition	HEART PALPITATIONS
Start date (dd MMM yyyy)	UN UNK 1983
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3642268

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Condition	LYME DISEASE
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

US3642268

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Condition	WRIST FRACTURE
Start date (dd MMM yyyy)	UN OCT 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	18 OCT 2018
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	OCT 2018
Stop Year (derived)	2018

US3642268

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:10 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 15:10
Height ( <i>xxx.x</i> )	180.5 cm
Weight ( <i>xxx.x</i> )	78.3 kg
BMI ( <i>xxx.x</i> )	24.03296 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642268

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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.*

US3642268

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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



US3642268

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

<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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

US3642268

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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	VISIT1

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 114992

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 ☒

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Height	ND - Not Done
Weight	ND - Not Done

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 15:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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)	21 SEP 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 16:52
Temperature (xxx.x)	96.1 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3642268

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 SEP 2020

What was the treatment time? (00:00-23:59) 16:14 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 16:14

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



US3642268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

15:55 (24 HR)

Collection date and time (derived)

21 SEP 2020 15:55

US3642268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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	16:00	21 SEP 2020 16:00
Nasopharyngeal Swab 2	No		

US3642268

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

21 SEP 2020 16:42

PC Open Date & Time

21 SEP 2020 16:34

PC Close Date & Time

21 SEP 2020 19:04

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 20:07
PC Open Date & Time	21 SEP 2020 19:59
PC Close Date & Time	22 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

---

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 17:21

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

---

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:47

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

---

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 21:36

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:27

---

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 21:43

---

PC Open Date & Time 25 SEP 2020 12:00

---

PC Close Date & Time 26 SEP 2020 11:59

---

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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 SEP 2020 22:49

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**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 16:44

PC Open Date & Time

21 SEP 2020 16:34

PC Close Date & Time

21 SEP 2020 19:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 20:08

PC Open Date & Time

21 SEP 2020 19:59

PC Close Date & Time

22 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 17:22

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 19:48

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 21:37

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 21:43

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 22:49

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 16:45
PC Open Date & Time	21 SEP 2020 16:34
PC Close Date & Time	21 SEP 2020 19:04

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 20:09
PC Open Date & Time	21 SEP 2020 19:59
PC Close Date & Time	22 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

47 of 1055



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

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

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 1055

EAB) (1725)

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 19:48
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 21:37
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

		Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 21:43	
PC Open Date & Time	25 SEP 2020 12:00	
PC Close Date & Time	26 SEP 2020 11:59	

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 22:50
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3642268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3642268

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 14:17
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

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

US3642268

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3642268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 18:32:15

Generated On: 11 Aug 2021 22:58:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

15:16 (24 HR)

Collection date and time (derived)

21 OCT 2020 15:16

US3642268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 18:32:15

Generated On: 11 Aug 2021 22:58:27

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	21 OCT 2020 15:20
Nasopharyngeal Swab 2	No		



US3642268

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:15

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3642268**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3642268**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3642268**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 15:10
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642268

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3642268

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 NOV 2020

Collection time (00:00-23:59)

15:20 (24 HR)

Collection date and time (derived)

16 NOV 2020 15:20

US3642268

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:45

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59



US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 DEC 2020 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 DEC 2020 23:59

---

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

09 DEC 2020 00:01

---

[Patient Cloud Close Date & Time](#)

---

13 DEC 2020 23:59

---

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 14:32:14

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 14:31:04
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 22:32:13

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 JAN 2021 14:33:57
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59



US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 14:42:40
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 12:00:34

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 14:30:51

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 07:20:41

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 12:01:35
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 11:20:02

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 04:40:58

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 166

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

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

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



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 11:52:25

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 07:14:51

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 MAR 2021 23:59

---

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

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

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 12:20:11

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59



US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 208

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

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

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

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3642268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 14:31:58

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3642268

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:58:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		12 MAR 2021 11:52:35

US3642268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642268

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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*

US3642268

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:53:25

Generated On: 11 Aug 2021 22:58:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:53:25

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 00:02:58

Generated On: 11 Aug 2021 22:58:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642268

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 00:02:58

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

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

Visit date (dd MMM yyyy)	19 APR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_



US3642268

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3642268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 APR 2021

Collection time (00:00-23:59)

15:30 (24 HR)

Collection date and time (derived)

19 APR 2021 15:30

US3642268

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3642268**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3642268**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642268

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:58:27

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

**US3642268**

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

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

**Generated On: 11 Aug 2021 22:58:27**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3642268

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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

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

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

Folder OID	UNBLND_DECIDE
------------	---------------



US3642268

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 02:23:51

Generated On: 11 Aug 2021 22:58:27

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

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 26 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3642268

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

15:47 (24 HR)

Collection date and time (derived)

26 JAN 2021 15:47

US3642268

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

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

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

Collection time (00:00 - 23:59)	15:53
---------------------------------	-------

Collection Date and Time (derived)	26 JAN 2021 15:53
------------------------------------	-------------------

US3642268

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

---

Did the participant experience any adverse events?

Yes ☒  
No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

AEID	
Adverse event	PERIPHERAL NEUROPATHY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 SEP 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)	04 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" 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 checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

---

PATIENT REPORTED LEFT SIDE  
PAIN IN LEG AND FOOT  
FOLLOWING INJECTION  
(INJECTION GIVEN IN LEFT  
ARM). PAIN IN LEG REPORTED  
WHEN LYING ON LEFT SIDE.  
WHEN PRESSING ON INJECTION  
SITE, PATIENT NOTICED NERVE  
PAIN SHOOTING DOWN LEG.  
BURNING, TINGLING, AND PAIN  
REPORTED IN LEG AND BOTH  
FEET, SPECIFICALLY ON THE  
SOLES OF THE FEET.  
OCCURRED DAILY, THEN  
REDUCED TO EVERY OTHER  
DAY, THEN 2 TIMES PER WEEK.  
SYMPTOMS STARTED AFTER  
VACCINATION AND HAVE  
PERSISTED. SYMPTOMS  
INTERFERED WITH ABILITY TO  
EXERCISE FOR SEVERAL  
WEEKS FOLLOWING THE  
INJECTION. SYMPTOMS HAVE  
RESOLVED AS OF 04 NOV 2020  
WITHOUT FURTHER  
SEQUELLAE.

---

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

---

---

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

AEID

Adverse event

LACERATION AND  
DISLOCATION OF THE RIGHT  
TOE

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)

01 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

143 of 1055

EAB) (1725)



US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

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

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

---

SUBJECT REPORTS THAT HE  
HAD TO GO TO THE ER ON  
01JAN2021 TO GET HELP FOR A  
LACERATION?AND  
DISLOCATION OF HIS RIGHT  
TOE. HE STATES THAT HE  
ACCIDENTALLY STEPPED ON A  
SHARP DEVICE AT HOME  
CAUSING INJURY.THE TOE IS  
NOW REPAIRED  
(NON-SURGICAL REPAIR) AND  
SUBJECT WILL CONTINUE TO  
REMAIN ON THE STUDY.

---

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)	

---

---

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 21:12:57

Generated On: 11 Aug 2021 22:58:27

---

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

Yes ☒

No ☐

---

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

---

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PERIPHERAL NEUROPATHY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

147 of 1055

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Name of Medication CEFALEXIN

Prophylaxis Yes ☒  
No ☐

Indication INFECTION OF THE TOE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

149 of 1055

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication LACERATION AND  
DISLOCATION OF RIGHT TOE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

151 of 1055



US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

153 of 1055

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 20:52:38

Generated On: 11 Aug 2021 22:58:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3642268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 18:32:14

Generated On: 11 Aug 2021 22:58:27

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3642268

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 13 Mar 2021 02:23:51

Generated On: 11 Aug 2021 22:58:27

---

Date of dosing discontinuation (dd MMM yyyy) 21 OCT 2020

---

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE # 1

---

US3642268

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 03 May 2021 21:24:18

Generated On: 11 Aug 2021 22:58:27

Date of study discontinuation/completion (dd MMM yyyy) 30 APR 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input checked="" type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

PARTICIPANT RECEIVED  
COVID-19 VACCINE OUTSIDE  
OF STUDY THROUGH EUA

If reason for discontinuation is Death, main cause of death

Adverse event ☐  
Unknown ☐  
Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐  
No ☐  
Unknown ☐

Audit

US3642268 (Prod: University of California San Diego)

**US3642268**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:58:27**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'US3642268'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 22:35:23



**US3642268**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:40:32

**US3642268**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 22:35:24

US3642268

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4)	21 Sep 2020 22:40:32

**US3642268**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'SCRN'	System	21 Sep 2020 22:40:32

US3642268

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered (b) (6) 1982'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 22:35:26

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '38'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'YEARS'	System	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '38'	System	21 Sep 2020 22:41:12



**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Male (M)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

US3642268

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

US3642268

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'I'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01



**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

**US3642268**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:27**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:01

US3642268

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:12

**US3642268**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Sep 2020'	System	21 Sep 2020 22:41:12

**US3642268**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2020'	System	21 Sep 2020 22:41:12

US3642268

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Amendment 3 (3)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:12

US3642268

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:12



**US3642268**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:27**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:12

**US3642268**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:27**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:12

**US3642268**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:27**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:12

US3642268

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 22:35:24

**US3642268**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:27**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'I'	System	21 Sep 2020 22:41:17

US3642268

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:17

US3642268

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:58:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Son Do (b) (4)	21 Oct 2020 17:37:33
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:28:56

US3642268

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 06:42:31
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'this information is not available in the medical record.' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Feb 2021 17:24:35
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:26:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Wrist surgery, LLT: Wrist surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:39:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:39:44
Data point term sent to Coder	System	21 Oct 2020 17:38:58
User entered 'wrist surgery'	Son Do (b) (4)	21 Oct 2020 17:38:11



**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '18 Oct 2018'	Son Do (b) (4)	21 Oct 2020 17:38:11

**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:38:11

**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	Son Do (b) (4)	21 Oct 2020 17:38:11

US3642268

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
	System	21 Oct 2020 17:38:42
User entered '18 Oct 2018' reason for change: Data Entry Error	Son Do (b) (4)	21 Oct 2020 17:38:42
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	21 Oct 2020 17:38:11
User entered 'UN Oct 2018'	Son Do (b) (4)	21 Oct 2020 17:38:11

**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:38:11

**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Oct 2018'	System	21 Oct 2020 17:38:11

**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2018'	System	21 Oct 2020 17:38:11

**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Oct 2018'	System	21 Oct 2020 17:38:11



**US3642268**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2018'	System	21 Oct 2020 17:38:11

US3642268

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:40:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:40:33
Data point term sent to Coder	System	21 Oct 2020 17:40:01
User entered 'vasectomy'	Son Do (b) (4)	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN Dec 2017'	Son Do (b) (4)	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	Son Do (b) (4)	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN Dec 2017'	Son Do (b) (4)	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Dec 2017'	System	21 Oct 2020 17:39:10



**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2017'	System	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Dec 2017'	System	21 Oct 2020 17:39:10

**US3642268**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2017'	System	21 Oct 2020 17:39:10

US3642268

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User coded data point as SOC: Reproductive system and breast disorders, HLG: Male reproductive tract infections and inflammations, HLT: Prostate and seminal vesicles infections and inflammations, PT: Prostatitis, LLT: Prostatitis - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 17:40:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 17:40:34
Data point term sent to Coder	System	21 Oct 2020 17:40:02
User entered 'prostatitis'	Son Do (b) (4)	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN UNK 2007'	Son Do (b) (4)	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	Son Do (b) (4)	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN UNK 2007'	Son Do (b) (4)	21 Oct 2020 17:39:37



**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Jan 2007'	System	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2007'	System	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Jan 2007'	System	21 Oct 2020 17:39:37

**US3642268**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2007'	System	21 Oct 2020 17:39:37

US3642268

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitations - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:41:38
Data point term sent to Coder	System	21 Oct 2020 17:41:05
User entered 'heart palpitations'	Son Do (b) (4)	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN UNK 1983'	Son Do (b) (4)	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:40:33



**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	Son Do (b) (4)	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN UNK 1996'	Son Do (b) (4)	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Jan 1983'	System	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '1983'	System	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Jan 1996'	System	21 Oct 2020 17:40:33

**US3642268**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '1996'	System	21 Oct 2020 17:40:33

US3642268

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:58:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Borrelial infections, PT: Lyme disease, LLT: Lyme disease - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:41:38
Data point term sent to Coder	System	21 Oct 2020 17:41:06
User entered 'lyme disease'	Son Do (b) (4)	21 Oct 2020 17:41:00



**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN UNK 1994'	Son Do (b) (4)	21 Oct 2020 17:41:00

**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:41:00

**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	Son Do (b) (4)	21 Oct 2020 17:41:00

**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'UN UNK 1994'	Son Do (b) (4)	21 Oct 2020 17:41:00

**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	Son Do (b) (4)	21 Oct 2020 17:41:00

**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Jan 1994'	System	21 Oct 2020 17:41:00

**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '1994'	System	21 Oct 2020 17:41:00

**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Jan 1994'	System	21 Oct 2020 17:41:00



**US3642268**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '1994'	System	21 Oct 2020 17:41:00

US3642268

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:58:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 22:22:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 22:22:40
Data point term sent to Coder	System	19 Apr 2021 22:22:05
User entered 'wrist fracture'	Colleen McLellan (b) (4)	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered 'un Oct 2018'	(b) (4) Colleen McLellan (b) (4)	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered '0'	Colleen McLellan (b) (4)	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered 'No (N)'	(b) (4) Colleen McLellan (b) (4)	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered '18 Oct 2018'	(b) (4) Colleen McLellan (b) (4)	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered '0'	Colleen McLellan (b) (4)	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Oct 2018'	System	19 Apr 2021 22:21:29



**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2018'	System	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'Oct 2018'	System	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '2018'	System	19 Apr 2021 22:21:29

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 15:30:21

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	Son Do (b) (4)	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15:10'	Son Do (b) (4)	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '21 Sep 2020 15:10'	System	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '180.5' cm	(b) (4)	23 Sep 2020 15:30:21
DataPoint set to visible.	Son Do (b) (4)	21 Sep 2020 22:41:17
	System	



US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '78.3' kg	(b) (4)	23 Sep 2020 15:30:21
DataPoint set to visible.	Son Do (b) (4)	21 Sep 2020 22:41:17
	System	

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '24.03296'	System	23 Sep 2020 15:30:21
DataPoint set to visible.	System	21 Sep 2020 22:41:17

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'kg/m2'	System	23 Sep 2020 15:30:21
DataPoint set to visible.	System	21 Sep 2020 22:41:17

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:26
User entered '97.9' F	Son Do (b) (4)	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	21 Oct 2020 17:41:26
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Son Do (b) (4)	23 Sep 2020 15:30:21

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:26
User entered '60'	Son Do (b) (4)	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'bpm'	System	23 Sep 2020 15:30:21



US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:26
User entered '18'	Son Do (b) (4)	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'breaths/min'	System	23 Sep 2020 15:30:21

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:26
User entered '127'	Son Do (b) (4)	23 Sep 2020 15:30:21

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'mmHg'	System	23 Sep 2020 15:30:21

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:26
User entered '74'	Son Do (b) (4)	23 Sep 2020 15:30:21

**US3642268**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'mmHg'	System	23 Sep 2020 15:30:21

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07

US3642268

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07



**US3642268**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:27**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 15:29:37

**US3642268**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:27**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	Son Do (b) (4)	23 Sep 2020 15:29:37

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34



US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 15:33:09
User entered 'No (N)' reason for change: Data Entry Son Do Error	System	23 Sep 2020 15:33:09
User opened query 'Data is required. Please complete.' (Site from System).	Son Do (b) (4)	23 Sep 2020 15:32:34
User entered empty.	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	Son Do (b) (4)	23 Sep 2020 15:32:34



US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'I'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '0'	Son Do (b) (4)	23 Sep 2020 15:32:34

US3642268

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Son Do (b) (4)	23 Sep 2020 15:32:34

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:37



US3642268

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:37

US3642268

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:41:37

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'VISIT1'	System	21 Sep 2020 22:41:37

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 22:35:27

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '114992'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 22:35:27

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 22:35:27

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:42:23

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:42:23



US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:42:23

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:58:27**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:42:23

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:42:23

US3642268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:27

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 22:42:23
DataPoint set to visible.	(b) (4) System	21 Sep 2020 22:41:12

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:38
User entered '180.5' cm	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:38
User entered '78.3' kg	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:38
User entered '180.5' cm	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:38
User entered '78.3' kg	Son Do (b) (4)	23 Sep 2020 15:31:14



US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	Son Do (b) (4)	23 Sep 2020 15:31:14

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:27**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15:10'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Sep 2020 15:10'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '97.9' F	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Son Do (b) (4)	23 Sep 2020 15:31:14



US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '60'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'bpm'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '18'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'breaths/min'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '127'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '74'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	23 Sep 2020 15:31:14



US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:38
User entered '180.5' cm	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 17:41:38
User entered '78.3' kg	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '16:52'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Sep 2020 16:52'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:17
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs; no ae required' (Site from System).	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 17:48:53
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Sep 2020 15:31:14
User entered '96.1' F	Son Do (b) (4)	23 Sep 2020 15:31:14



US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '59'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'bpm'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '18'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'breaths/min'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '124'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	23 Sep 2020 15:31:14



US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '74'	Son Do (b) (4)	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	23 Sep 2020 15:31:14

US3642268

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Megan Loughran (b) (4)	24 Nov 2020 19:55:12
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 15:29:47

US3642268

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty; reason for change Data Entry Error	(b) (4) Megan Loughran (b) (4)	24 Nov 2020 19:55:12
User entered '21 Sep 2020'	Son Do (b) (4)	23 Sep 2020 15:29:47

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 23:22:29



US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '16:14'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Sep 2020 16:14'	System	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Megan Loughran (b) (4)	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'ONCE'	System	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 23:22:29

US3642268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 15:31:45

US3642268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	Son Do (b) (4)	23 Sep 2020 15:31:45



**US3642268**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:27**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15:55'	Son Do (b) (4)	23 Sep 2020 15:31:45

US3642268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Sep 2020 15:55'	System	23 Sep 2020 15:31:45

US3642268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:58:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Sep 2020'	Son Do (b) (4)	23 Sep 2020 15:31:57

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	23 Sep 2020 15:31:57

US3642268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 15:31:57

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:27**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '16:00'	Son Do (b) (4)	23 Sep 2020 15:31:57

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Sep 2020 16:00'	System	23 Sep 2020 15:31:57

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	23 Sep 2020 15:31:57



US3642268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:31:57

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:27**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Son Do (b) (4)	23 Sep 2020 15:31:57

US3642268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	23 Sep 2020 15:31:57

US3642268

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:30:15

**US3642268**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	29 Sep 2020 21:30:15

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:42:11', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'fa05e5a4-38fa-4a3e-b03a-0511a2ef2996'	System	21 Sep 2020 23:42:34
User entered 'Yes (Y)'	System	21 Sep 2020 23:42:34

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:42:18', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'fa05e5a4-38fa-4a3e-b03a-0511a2ef2996'	System	21 Sep 2020 23:42:34
User entered '96.1'	System	21 Sep 2020 23:42:34



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:42:22', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'fa05e5a4-38fa-4a3e-b03a-0511a2ef2996'	System	21 Sep 2020 23:42:34
User entered 'No (N)'	System	21 Sep 2020 23:42:34

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:42:29', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'fa05e5a4-38fa-4a3e-b03a-0511a2ef2996'	System	21 Sep 2020 23:42:34
User entered '21 Sep 2020 16:42'	System	21 Sep 2020 23:42:34

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 16:34'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 19:04'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:07:18', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2c2bbaeb-4e7e-4c37-854b-dedb80c6901e'	System	22 Sep 2020 03:07:32
User entered 'Yes (Y)'	System	22 Sep 2020 03:07:32

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:07:22', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2c2bbaeb-4e7e-4c37-854b-dedb80c6901e' User entered '97.7'	System	22 Sep 2020 03:07:32
	System	22 Sep 2020 03:07:32

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:07:25', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2c2bbaeb-4e7e-4c37-854b-dedb80c6901e'	System	22 Sep 2020 03:07:32
User entered 'No (N)'	System	22 Sep 2020 03:07:32



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:07:30', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2c2bbaeb-4e7e-4c37-854b-dedb80c6901e'	System	22 Sep 2020 03:07:32
User entered '21 Sep 2020 20:07'	System	22 Sep 2020 03:07:32

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 19:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 2'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:21:04', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'f1d04ced-6075-4fb7-9499-d387c0328141'	System	23 Sep 2020 00:21:22
User entered 'Yes (Y)'	System	23 Sep 2020 00:21:22

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:21:08', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'f1d04ced-6075-4fb7-9499-d387c0328141'	System	23 Sep 2020 00:21:22
User entered '98.3'	System	23 Sep 2020 00:21:22

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:21:11', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'f1d04ced-6075-4fb7-9499-d387c0328141'	System	23 Sep 2020 00:21:22
User entered 'No (N)'	System	23 Sep 2020 00:21:22

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:21:15', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'f1d04ced-6075-4fb7-9499-d387c0328141'	System	23 Sep 2020 00:21:22
User entered '22 Sep 2020 17:21'	System	23 Sep 2020 00:21:22



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 3'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:47:28', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6a958e3d-46f4-4543-925a-25c4c7a2d4ef'	System	24 Sep 2020 02:47:43
User entered 'Yes (Y)'	System	24 Sep 2020 02:47:43

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:47:32', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6a958e3d-46f4-4543-925a-25c4c7a2d4ef' User entered '97.2'	System	24 Sep 2020 02:47:43
	System	24 Sep 2020 02:47:43

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:47:35', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6a958e3d-46f4-4543-925a-25c4c7a2d4ef'	System	24 Sep 2020 02:47:43
User entered 'No (N)'	System	24 Sep 2020 02:47:43

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:47:39', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6a958e3d-46f4-4543-925a-25c4c7a2d4ef'	System	24 Sep 2020 02:47:43
User entered '23 Sep 2020 19:47'	System	24 Sep 2020 02:47:43

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 23:22:29



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 4'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:24', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '38892304-4874-4401-af9a-6d1b4ae60b93'	System	25 Sep 2020 04:36:39
User entered 'Yes (Y)'	System	25 Sep 2020 04:36:39

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:29', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '38892304-4874-4401-af9a-6d1b4ae60b93'	System	25 Sep 2020 04:36:39
User entered '98.4'	System	25 Sep 2020 04:36:39

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:31', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '38892304-4874-4401-af9a-6d1b4ae60b93'	System	25 Sep 2020 04:36:39
User entered 'No (N)'	System	25 Sep 2020 04:36:39

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:35', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '38892304-4874-4401-af9a-6d1b4ae60b93'	System	25 Sep 2020 04:36:39
User entered '24 Sep 2020 21:36'	System	25 Sep 2020 04:36:39

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 23:22:29



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 5'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:15', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '0e014c91-82dd-4005-97ca-3f9da9a22f72'	System	26 Sep 2020 04:43:22
User entered 'No (N)'	System	26 Sep 2020 04:43:22

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:17', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '0e014c91-82dd-4005-97ca-3f9da9a22f72'	System	26 Sep 2020 04:43:22
User entered 'No (N)'	System	26 Sep 2020 04:43:22

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:19', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '0e014c91-82dd-4005-97ca-3f9da9a22f72'	System	26 Sep 2020 04:43:22
User entered '25 Sep 2020 21:43'	System	26 Sep 2020 04:43:22

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 6'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 7'	System	21 Sep 2020 23:22:29



US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:17', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '296df1cc-c1ad-401e-8263-92202e08ce93'	System	28 Sep 2020 05:49:32
User entered 'Yes (Y)'	System	28 Sep 2020 05:49:32

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:22', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '296df1cc-c1ad-401e-8263-92202e08ce93'	System	28 Sep 2020 05:49:32
User entered '98.6'	System	28 Sep 2020 05:49:32

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:25', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '296df1cc-c1ad-401e-8263-92202e08ce93'	System	28 Sep 2020 05:49:32
User entered 'No (N)'	System	28 Sep 2020 05:49:32

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:27', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '296df1cc-c1ad-401e-8263-92202e08ce93'	System	28 Sep 2020 05:49:32
User entered '27 Sep 2020 22:49'	System	28 Sep 2020 05:49:32

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:44:18', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '966ef0b2-9466-4fdb-8238-6cccd75bd247'	System	21 Sep 2020 23:45:04
User entered 'None (1)'	System	21 Sep 2020 23:45:04



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:44:30', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '966ef0b2-9466-4fdb-8238-6cccd75bd247'	System	21 Sep 2020 23:45:04
User entered 'No (N)'	System	21 Sep 2020 23:45:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:44:34', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '966ef0b2-9466-4fdb-8238-6cccd75bd247'	System	21 Sep 2020 23:45:04
User entered 'No (N)'	System	21 Sep 2020 23:45:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:44:50', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '966ef0b2-9466-4fdb-8238-6cccd75bd247'	System	21 Sep 2020 23:45:04
User entered 'None (1)'	System	21 Sep 2020 23:45:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:44:59', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '966ef0b2-9466-4fdb-8238-6cccd75bd247'	System	21 Sep 2020 23:45:04
User entered '21 Sep 2020 16:44'	System	21 Sep 2020 23:45:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 16:34'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 19:04'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:07:52', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c799d0b-8c05-4036-a2d4-a758c644c540'	System	22 Sep 2020 03:08:44
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 03:08:44



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:05', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c799d0b-8c05-4036-a2d4-a758c644c540'	System	22 Sep 2020 03:08:44
User entered 'No (N)'	System	22 Sep 2020 03:08:44

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:25', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c799d0b-8c05-4036-a2d4-a758c644c540'	System	22 Sep 2020 03:08:44
User entered 'No (N)'	System	22 Sep 2020 03:08:44

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:37', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c799d0b-8c05-4036-a2d4-a758c644c540'	System	22 Sep 2020 03:08:44
User entered 'None (1)'	System	22 Sep 2020 03:08:44

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:40', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c799d0b-8c05-4036-a2d4-a758c644c540'	System	22 Sep 2020 03:08:44
User entered '21 Sep 2020 20:08'	System	22 Sep 2020 03:08:44

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 19:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 2'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:21:59', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '8b587c77-d004-4c4c-b918-7cba2c136435'	System	23 Sep 2020 00:22:44
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 00:22:44



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:01', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '8b587c77-d004-4c4c-b918-7cba2c136435'	System	23 Sep 2020 00:22:44
User entered 'No (N)'	System	23 Sep 2020 00:22:44

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:27', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '8b587c77-d004-4c4c-b918-7cba2c136435'	System	23 Sep 2020 00:22:44
User entered 'No (N)'	System	23 Sep 2020 00:22:44

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:38', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '8b587c77-d004-4c4c-b918-7cba2c136435'	System	23 Sep 2020 00:22:44
User entered 'None (1)'	System	23 Sep 2020 00:22:44

**US3642268**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:40', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '8b587c77-d004-4c4c-b918-7cba2c136435'	System	23 Sep 2020 00:22:44
User entered '22 Sep 2020 17:22'	System	23 Sep 2020 00:22:44

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 3'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:47:54', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c5eb399-561d-4abc-ba3c-3a9d74055b46'	System	24 Sep 2020 02:48:31
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 02:48:31



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:47:58', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c5eb399-561d-4abc-ba3c-3a9d74055b46'	System	24 Sep 2020 02:48:31
User entered 'No (N)'	System	24 Sep 2020 02:48:31

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:12', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c5eb399-561d-4abc-ba3c-3a9d74055b46'	System	24 Sep 2020 02:48:31
User entered 'No (N)'	System	24 Sep 2020 02:48:31

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:24', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c5eb399-561d-4abc-ba3c-3a9d74055b46'	System	24 Sep 2020 02:48:31
User entered 'None (1)'	System	24 Sep 2020 02:48:31

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:26', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '1c5eb399-561d-4abc-ba3c-3a9d74055b46'	System	24 Sep 2020 02:48:31
User entered '23 Sep 2020 19:48'	System	24 Sep 2020 02:48:31

**US3642268**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 4'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:49', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '627b9055-e8a9-473d-9595-09a79345017a'	System	25 Sep 2020 04:37:04
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 04:37:04



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:51', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '627b9055-e8a9-473d-9595-09a79345017a'	System	25 Sep 2020 04:37:04
User entered 'No (N)'	System	25 Sep 2020 04:37:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:53', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '627b9055-e8a9-473d-9595-09a79345017a'	System	25 Sep 2020 04:37:04
User entered 'No (N)'	System	25 Sep 2020 04:37:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:36:59', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '627b9055-e8a9-473d-9595-09a79345017a'	System	25 Sep 2020 04:37:04
User entered 'None (1)'	System	25 Sep 2020 04:37:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:01', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '627b9055-e8a9-473d-9595-09a79345017a'	System	25 Sep 2020 04:37:04
User entered '24 Sep 2020 21:37'	System	25 Sep 2020 04:37:04

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 5'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:25', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '323e1300-a7ec-4a1b-8b7c-57cc8ddc1f1a'	System	26 Sep 2020 04:43:37
User entered 'None (1)'	System	26 Sep 2020 04:43:37



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:28', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '323e1300-a7ec-4a1b-8b7c-57cc8ddc1f1a'	System	26 Sep 2020 04:43:37
User entered 'No (N)'	System	26 Sep 2020 04:43:37

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:30', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '323e1300-a7ec-4a1b-8b7c-57cc8ddc1f1a'	System	26 Sep 2020 04:43:37
User entered 'No (N)'	System	26 Sep 2020 04:43:37

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:32', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '323e1300-a7ec-4a1b-8b7c-57cc8ddc1f1a'	System	26 Sep 2020 04:43:37
User entered 'None (1)'	System	26 Sep 2020 04:43:37

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:34', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '323e1300-a7ec-4a1b-8b7c-57cc8ddc1f1a'	System	26 Sep 2020 04:43:37
User entered '25 Sep 2020 21:43'	System	26 Sep 2020 04:43:37

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 6'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 23:22:29



US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 7'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:41', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a5bbc08d-7762-4b1f-871c-7177e8ce3067'	System	28 Sep 2020 05:50:02
User entered 'None (1)'	System	28 Sep 2020 05:50:02

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:44', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a5bbc08d-7762-4b1f-871c-7177e8ce3067'	System	28 Sep 2020 05:50:02
User entered 'No (N)'	System	28 Sep 2020 05:50:02

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:47', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a5bbc08d-7762-4b1f-871c-7177e8ce3067'	System	28 Sep 2020 05:50:02
User entered 'No (N)'	System	28 Sep 2020 05:50:02

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:56', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a5bbc08d-7762-4b1f-871c-7177e8ce3067'	System	28 Sep 2020 05:50:02
User entered 'None (1)'	System	28 Sep 2020 05:50:02

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:49:58', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a5bbc08d-7762-4b1f-871c-7177e8ce3067'	System	28 Sep 2020 05:50:02
User entered '27 Sep 2020 22:49'	System	28 Sep 2020 05:50:02

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 23:22:29



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:07', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered 'None (0)'	System	21 Sep 2020 23:45:40

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:11', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered 'None (0)'	System	21 Sep 2020 23:45:40

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:15', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered 'None (0)'	System	21 Sep 2020 23:45:40

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:19', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered 'None (0)'	System	21 Sep 2020 23:45:40

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:22', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered 'None (0)'	System	21 Sep 2020 23:45:40

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:26', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered 'None (0)'	System	21 Sep 2020 23:45:40

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:32', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered 'No (N)'	System	21 Sep 2020 23:45:40



**US3642268**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T16:45:38', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'a7d4ab17-fcb1-4e26-a9d4-285a5c12f776'	System	21 Sep 2020 23:45:40
User entered '21 Sep 2020 16:45'	System	21 Sep 2020 23:45:40

**US3642268**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 16:34'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 19:04'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:46', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered 'None (0)'	System	22 Sep 2020 03:09:13

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:50', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered 'None (0)'	System	22 Sep 2020 03:09:13

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:56', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered 'None (0)'	System	22 Sep 2020 03:09:13

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:08:59', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered 'None (0)'	System	22 Sep 2020 03:09:13



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:09:01', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered 'None (0)'	System	22 Sep 2020 03:09:13

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:09:02', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered 'None (0)'	System	22 Sep 2020 03:09:13

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:09:08', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered 'No (N)'	System	22 Sep 2020 03:09:13

**US3642268**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-21T20:09:11', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '95680cbd-2a75-4f09-ac80-a1db9931aed1'	System	22 Sep 2020 03:09:13
User entered '21 Sep 2020 20:09'	System	22 Sep 2020 03:09:13

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '21 Sep 2020 19:59'	System	21 Sep 2020 23:22:29

**US3642268**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 2'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:46', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered 'None (0)'	System	23 Sep 2020 00:23:08



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:49', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered 'No interference with activity (1)'	System	23 Sep 2020 00:23:08

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:52', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered 'None (0)'	System	23 Sep 2020 00:23:08

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:54', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered 'None (0)'	System	23 Sep 2020 00:23:08

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:56', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered 'None (0)'	System	23 Sep 2020 00:23:08

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:22:57', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered 'None (0)'	System	23 Sep 2020 00:23:08

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:23:01', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered 'No (N)'	System	23 Sep 2020 00:23:08

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-22T17:23:03', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5e96deaa-fcc3-49f6-b8fd-32ec18bdb95a'	System	23 Sep 2020 00:23:08
User entered '22 Sep 2020 17:23'	System	23 Sep 2020 00:23:08

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 23:22:29



**US3642268**

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

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

**Generated On: 11 Aug 2021 22:58:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 3'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:30', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered 'None (0)'	System	24 Sep 2020 02:48:49

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:32', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered 'No interference with activity (1)'	System	24 Sep 2020 02:48:49

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:35', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered 'None (0)'	System	24 Sep 2020 02:48:49

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:38', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered 'No interference with activity (1)'	System	24 Sep 2020 02:48:49

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:40', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered 'None (0)'	System	24 Sep 2020 02:48:49

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:42', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered 'None (0)'	System	24 Sep 2020 02:48:49



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:44', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered 'No (N)'	System	24 Sep 2020 02:48:49

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-23T19:48:47', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '54998d6b-4dcd-4c64-94de-d63840ee364d'	System	24 Sep 2020 02:48:49
User entered '23 Sep 2020 19:48'	System	24 Sep 2020 02:48:49

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

**US3642268**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 4'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:08', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered 'None (0)'	System	25 Sep 2020 04:37:31

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:12', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered 'None (0)'	System	25 Sep 2020 04:37:31

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:16', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered 'None (0)'	System	25 Sep 2020 04:37:31



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:17', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered 'None (0)'	System	25 Sep 2020 04:37:31

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:19', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered 'None (0)'	System	25 Sep 2020 04:37:31

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:21', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered 'None (0)'	System	25 Sep 2020 04:37:31

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:23', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered 'No (N)'	System	25 Sep 2020 04:37:31

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-24T21:37:27', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18b6e71d-32e8-4771-bd57-1a66ad5d9e03'	System	25 Sep 2020 04:37:31
User entered '24 Sep 2020 21:37'	System	25 Sep 2020 04:37:31

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 5'	System	21 Sep 2020 23:22:29



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:39', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered 'None (0)'	System	26 Sep 2020 04:43:57

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:42', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered 'None (0)'	System	26 Sep 2020 04:43:57

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:45', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered 'None (0)'	System	26 Sep 2020 04:43:57

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:46', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered 'None (0)'	System	26 Sep 2020 04:43:57

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:48', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered 'None (0)'	System	26 Sep 2020 04:43:57

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:49', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered 'None (0)'	System	26 Sep 2020 04:43:57

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:52', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered 'No (N)'	System	26 Sep 2020 04:43:57

**US3642268**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-25T21:43:54', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '81d3f989-ac25-4e83-9083-5be00d0edfb3'	System	26 Sep 2020 04:43:57
User entered '25 Sep 2020 21:43'	System	26 Sep 2020 04:43:57



**US3642268**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

**US3642268**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 6'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46

**US3642268**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

**US3642268**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
Data entry locked.	System	21 Sep 2020 23:22:29
User entered 'Day 7'	System	21 Sep 2020 23:22:29

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:02', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered 'None (0)'	System	28 Sep 2020 05:50:21

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:04', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered 'None (0)'	System	28 Sep 2020 05:50:21



US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:06', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered 'None (0)'	System	28 Sep 2020 05:50:21

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:08', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered 'None (0)'	System	28 Sep 2020 05:50:21

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:09', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered 'None (0)'	System	28 Sep 2020 05:50:21

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:11', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered 'None (0)'	System	28 Sep 2020 05:50:21

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:14', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered 'No (N)'	System	28 Sep 2020 05:50:21

**US3642268**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-09-27T22:50:17', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ff8a456a-813f-485a-a42f-907af344a2dc'	System	28 Sep 2020 05:50:21
User entered '27 Sep 2020 22:50'	System	28 Sep 2020 05:50:21

US3642268

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 23:22:29

**US3642268**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:46
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 23:22:29



**US3642268**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:30:29

US3642268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:30:29

US3642268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:30:29

US3642268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:30:29

US3642268

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 21:30:35

US3642268

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	29 Sep 2020 21:30:35

**US3642268**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	06 Oct 2020 19:39:43

**US3642268**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '6 Oct 2020'	Colleen McLellan (b) (4)	06 Oct 2020 19:39:43



US3642268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	06 Oct 2020 19:39:43

US3642268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Colleen McLellan (b) (4)	06 Oct 2020 19:39:43

US3642268

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	06 Oct 2020 19:39:34

**US3642268**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	06 Oct 2020 19:39:34

**US3642268**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 16:48:05

US3642268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15 Oct 2020'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 16:48:05

US3642268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 16:48:05

US3642268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 16:48:05



US3642268

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 16:48:10

**US3642268**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	15 Oct 2020 16:48:10

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:08:51

US3642268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '21 Oct 2020'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:08:51

US3642268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:08:51

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'VISIT2'	System	21 Oct 2020 22:08:51

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:54:47



US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 14:54:47

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:27**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '14:17'	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Oct 2020 14:17'	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '98.2' F	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Oct 2020 14:54:47

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:27**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '69'	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'bpm'	System	23 Oct 2020 14:54:47



US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '20'	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'breaths/min'	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '118'	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '73'	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 14:54:47



US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:27**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:27**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	23 Oct 2020 14:54:47



US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	23 Oct 2020 14:54:47

US3642268

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:55:00

US3642268

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 14:55:00



US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User closed query 'Per CDM: The reason is dose withheld due to AE however no corresponding AE is seen recorded. Kindly update the data accordingly.Thank you.' (Site from DM).		22 Feb 2021 09:40:01
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
Query 'Per CDM: The reason is dose withheld due to AE however no corresponding AE is seen recorded. Kindly update the data accordingly.Thank you.'	(b) (4)	
answered with 'AE is in fact already recorded - see log line 1.' (Site from DM).	Megan Loughran (b) (4)	18 Feb 2021 16:46:22
	(b) (4)	
User opened query 'Per CDM: The reason is dose withheld due to AE however no corresponding AE is seen recorded. Kindly update the data accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:49:53
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Megan Loughran (b) (4)	21 Oct 2020 22:09:24
	(b) (4)	

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:09:24



US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	21 Oct 2020 22:09:24

US3642268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:55:15

US3642268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 14:55:15

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:27**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15:16'	Son Do (b) (4)	23 Oct 2020 14:55:15

US3642268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Oct 2020 15:16'	System	23 Oct 2020 14:55:15

US3642268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:58:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 14:55:27

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	23 Oct 2020 14:55:27



US3642268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:55:27

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:27**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15:20'	Son Do (b) (4)	23 Oct 2020 14:55:27

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '21 Oct 2020 15:20'	System	23 Oct 2020 14:55:27

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	23 Oct 2020 14:55:27

US3642268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 14:55:27

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:27**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:55:27

**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered empty.	System	23 Oct 2020 14:55:27

US3642268

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:55:35



**US3642268**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	23 Oct 2020 14:55:35

US3642268

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	17 Nov 2020 18:07:56

**US3642268**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	17 Nov 2020 18:07:56

US3642268

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	17 Nov 2020 18:08:04

US3642268

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	17 Nov 2020 18:08:04

US3642268

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	17 Nov 2020 18:08:10

**US3642268**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '1'	System	17 Nov 2020 18:08:10

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Yes (Y)'	Son Do (b) (4)	17 Nov 2020 18:08:22



**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '16 Nov 2020'	Son Do (b) (4)	17 Nov 2020 18:08:22

US3642268

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Clinic (Clinic)'	Son Do (b) (4)	17 Nov 2020 18:08:22

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'VISIT3'	System	17 Nov 2020 18:08:22

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Yes (Y)'	Son Do (b) (4)	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '16 Nov 2020'	Son Do (b) (4)	17 Nov 2020 18:08:43

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '15:10'	Son Do (b) (4)	17 Nov 2020 18:08:43

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '16 Nov 2020 15:10'	System	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '98.7' F	Son Do (b) (4)	17 Nov 2020 18:08:43



US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Oral (Oral)'	Son Do (b) (4)	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	17 Nov 2020 18:08:43

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '72'	Son Do (b) (4)	17 Nov 2020 18:08:43

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'bpm'	System	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '16'	Son Do (b) (4)	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'breaths/min'	System	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '118'	Son Do (b) (4)	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	17 Nov 2020 18:08:43



US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '65'	Son Do (b) (4)	17 Nov 2020 18:08:43

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'mmHg'	System	17 Nov 2020 18:08:43

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34

US3642268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34

US3642268

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'No (N)'	Son Do (b) (4)	17 Nov 2020 18:08:51

US3642268

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered empty.	Son Do (b) (4)	17 Nov 2020 18:08:51

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:27**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Yes (Y)'	Son Do (b) (4)	17 Nov 2020 18:09:03

US3642268

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '16 Nov 2020'	Son Do (b) (4)	17 Nov 2020 18:09:03



**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:27**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered '15:20'	Son Do (b) (4)	17 Nov 2020 18:09:03

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '16 Nov 2020 15:20'	System	17 Nov 2020 18:09:03

US3642268

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:45
User entered 'Yes (Y)'	Son Do (b) (4)	17 Nov 2020 18:09:08

**US3642268**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered '1'	System	17 Nov 2020 18:09:08

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-16T14:32:03', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '3aaaace5-cb64-4932-96f4-09ef49187a9a'	System	16 Dec 2020 22:32:19
User entered 'No (N)'	System	16 Dec 2020 22:32:19

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-16T14:32:10', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '3aaaace5-cb64-4932-96f4-09ef49187a9a'	System	16 Dec 2020 22:32:19
User entered 'No (N)'	System	16 Dec 2020 22:32:19

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-16T14:32:14', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '3aaaace5-cb64-4932-96f4-09ef49187a9a'	System	16 Dec 2020 22:32:19
User entered '16 Dec 2020 14:32:14'	System	16 Dec 2020 22:32:19

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-23T14:30:55', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6d2a475f-3684-4c3e-8404-15ac8b16ce06'	System	23 Dec 2020 22:31:10
User entered 'No (N)'	System	23 Dec 2020 22:31:10



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-23T14:31:01', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6d2a475f-3684-4c3e-8404-15ac8b16ce06'	System	23 Dec 2020 22:31:10
User entered 'No (N)'	System	23 Dec 2020 22:31:10

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-23T14:31:04', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6d2a475f-3684-4c3e-8404-15ac8b16ce06'	System	23 Dec 2020 22:31:10
User entered '23 Dec 2020 14:31:04'	System	23 Dec 2020 22:31:10

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-30T22:32:05', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6f1000e1-0f8f-4738-be69-4332c6f817c5'	System	31 Dec 2020 06:32:15
User entered 'No (N)'	System	31 Dec 2020 06:32:15

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-30T22:32:09', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6f1000e1-0f8f-4738-be69-4332c6f817c5'	System	31 Dec 2020 06:32:15
User entered 'No (N)'	System	31 Dec 2020 06:32:15

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2020-12-30T22:32:13', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '6f1000e1-0f8f-4738-be69-4332c6f817c5'	System	31 Dec 2020 06:32:15
User entered '30 Dec 2020 22:32:13'	System	31 Dec 2020 06:32:15



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-06T14:33:41', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2cf8dc51-3bed-475c-87e9-a472c2e6372f'	System	06 Jan 2021 22:34:10
User entered 'Yes (Y)'	System	06 Jan 2021 22:34:10

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-06T14:33:36', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2cf8dc51-3bed-475c-87e9-a472c2e6372f'	System	06 Jan 2021 22:34:10
User entered 'No (N)'	System	06 Jan 2021 22:34:10

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-06T14:33:35', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2cf8dc51-3bed-475c-87e9-a472c2e6372f'	System	06 Jan 2021 22:34:10
User entered 'No (N)'	System	06 Jan 2021 22:34:10

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-06T14:33:33', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2cf8dc51-3bed-475c-87e9-a472c2e6372f'	System	06 Jan 2021 22:34:10
User entered 'Yes (Y)'	System	06 Jan 2021 22:34:10

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-06T14:33:53', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2cf8dc51-3bed-475c-87e9-a472c2e6372f'	System	06 Jan 2021 22:34:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 22:34:10



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-06T14:33:57', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '2cf8dc51-3bed-475c-87e9-a472c2e6372f' User entered '06 Jan 2021 14:33:57'	System	06 Jan 2021 22:34:10

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-13T14:42:35', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '46a62687-d12e-4a98-85ba-94ad1e3f9b31'	System	13 Jan 2021 22:42:45
User entered 'No (N)'	System	13 Jan 2021 22:42:45

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-13T14:42:37', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '46a62687-d12e-4a98-85ba-94ad1e3f9b31'	System	13 Jan 2021 22:42:45
User entered 'No (N)'	System	13 Jan 2021 22:42:45

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-13T14:42:40', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '46a62687-d12e-4a98-85ba-94ad1e3f9b31'	System	13 Jan 2021 22:42:45
User entered '13 Jan 2021 14:42:40'	System	13 Jan 2021 22:42:45

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-22T12:00:29', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '4889956a-5597-4881-a61a-b37e0b8ccfc5'	System	22 Jan 2021 20:00:42
User entered 'No (N)'	System	22 Jan 2021 20:00:42

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-22T12:00:31', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '4889956a-5597-4881-a61a-b37e0b8ccfc5'	System	22 Jan 2021 20:00:42
User entered 'No (N)'	System	22 Jan 2021 20:00:42

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-22T12:00:34', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '4889956a-5597-4881-a61a-b37e0b8ccfc5' User entered '22 Jan 2021 12:00:34'	System	22 Jan 2021 20:00:42

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-27T14:30:46', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '0432340a-29c8-46db-8d48-0e990194eda3'	System	27 Jan 2021 22:30:55
User entered 'No (N)'	System	27 Jan 2021 22:30:55

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-27T14:30:48', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '0432340a-29c8-46db-8d48-0e990194eda3'	System	27 Jan 2021 22:30:55
User entered 'No (N)'	System	27 Jan 2021 22:30:55

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-01-27T14:30:51', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '0432340a-29c8-46db-8d48-0e990194eda3'	System	27 Jan 2021 22:30:55
User entered '27 Jan 2021 14:30:51'	System	27 Jan 2021 22:30:55

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-03T07:20:35', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5895e274-3f58-450f-8ddb-fb39ee38ef0b'	System	03 Feb 2021 15:20:47
User entered 'No (N)'	System	03 Feb 2021 15:20:47

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-03T07:20:37', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5895e274-3f58-450f-8ddb-fb39ee38ef0b'	System	03 Feb 2021 15:20:47
User entered 'No (N)'	System	03 Feb 2021 15:20:47



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-03T07:20:41', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '5895e274-3f58-450f-8ddb-fb39ee38ef0b'	System	03 Feb 2021 15:20:47
User entered '03 Feb 2021 07:20:41'	System	03 Feb 2021 15:20:47

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-12T12:01:29', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '506a5a33-9f41-4dc8-9095-46eed94902c'	System	12 Feb 2021 20:02:17
User entered 'No (N)'	System	12 Feb 2021 20:02:17

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-12T12:01:32', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '506a5a33-9f41-4dc8-9095-46eed94902c'	System	12 Feb 2021 20:02:17
User entered 'No (N)'	System	12 Feb 2021 20:02:17

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-12T12:01:35', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '506a5a33-9f41-4dc8-9095-46eed94902c' User entered '12 Feb 2021 12:01:35'	System	12 Feb 2021 20:02:17

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-17T11:19:57', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '85904324-62ad-467d-bb7f-48d4497d9870'	System	17 Feb 2021 19:20:07
User entered 'No (N)'	System	17 Feb 2021 19:20:07

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-17T11:19:59', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '85904324-62ad-467d-bb7f-48d4497d9870'	System	17 Feb 2021 19:20:07
User entered 'No (N)'	System	17 Feb 2021 19:20:07

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-17T11:20:02', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '85904324-62ad-467d-bb7f-48d4497d9870'	System	17 Feb 2021 19:20:07
User entered '17 Feb 2021 11:20:02'	System	17 Feb 2021 19:20:07

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-24T04:40:53-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18f769b0-50cd-4b4e-ace1-56ac9594a527'	System	24 Feb 2021 12:41:03
User entered 'No (N)'	System	24 Feb 2021 12:41:03

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-24T04:40:55-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18f769b0-50cd-4b4e-ace1-56ac9594a527'	System	24 Feb 2021 12:41:03
User entered 'No (N)'	System	24 Feb 2021 12:41:03

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-02-24T04:40:58-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '18f769b0-50cd-4b4e-ace1-56ac9594a527'	System	24 Feb 2021 12:41:03
User entered '24 Feb 2021 04:40:58'	System	24 Feb 2021 12:41:03

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-12T11:52:20-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '374ea7f0-4233-493c-8377-0148f6ed3630'	System	12 Mar 2021 19:52:29
User entered 'No (N)'	System	12 Mar 2021 19:52:29

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-12T11:52:23-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '374ea7f0-4233-493c-8377-0148f6ed3630'	System	12 Mar 2021 19:52:29
User entered 'No (N)'	System	12 Mar 2021 19:52:29

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-12T11:52:25-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '374ea7f0-4233-493c-8377-0148f6ed3630'	System	12 Mar 2021 19:52:29
User entered '12 Mar 2021 11:52:25'	System	12 Mar 2021 19:52:29

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-17T07:14:46-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'b1c88737-6d66-4a12-a046-ffc57cc1ddf6'	System	17 Mar 2021 14:14:54
User entered 'No (N)'	System	17 Mar 2021 14:14:54



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-17T07:14:48-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'b1c88737-6d66-4a12-a046-ffc57cc1ddf6'	System	17 Mar 2021 14:14:54
User entered 'No (N)'	System	17 Mar 2021 14:14:54

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-17T07:14:51-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'b1c88737-6d66-4a12-a046-ffc57cc1ddf6'	System	17 Mar 2021 14:14:54
User entered '17 Mar 2021 07:14:51'	System	17 Mar 2021 14:14:54

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-04-09T12:19:59-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '41026727-ac80-44cb-bcd1-26fdff4d9d87'	System	09 Apr 2021 19:20:16
User entered 'No (N)'	System	09 Apr 2021 19:20:16

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-04-09T12:20:08-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '41026727-ac80-44cb-bcd1-26fdff4d9d87'	System	09 Apr 2021 19:20:16
User entered 'No (N)'	System	09 Apr 2021 19:20:16

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-04-09T12:20:11-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '41026727-ac80-44cb-bcd1-26fdff4d9d87'	System	09 Apr 2021 19:20:16
User entered '09 Apr 2021 12:20:11'	System	09 Apr 2021 19:20:16

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 10:04:39



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-04-28T14:31:52-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '11d01bd3-3cce-4345-be14-4de3ea050623' User entered 'No (N)'	System	28 Apr 2021 21:32:03
	System	28 Apr 2021 21:32:03



**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-04-28T14:31:55-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '11d01bd3-3cce-4345-be14-4de3ea050623'	System	28 Apr 2021 21:32:03
User entered 'No (N)'	System	28 Apr 2021 21:32:03

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-04-28T14:31:58-07:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: '11d01bd3-3cce-4345-be14-4de3ea050623' User entered '28 Apr 2021 14:31:58'	System	28 Apr 2021 21:32:03
	System	28 Apr 2021 21:32:03

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 10:04:39

**US3642268**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:04:39
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 10:04:39

US3642268

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:58:27**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-12T11:52:32-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ac35e2d8-e14f-432d-a068-5f055e83035e'	System	12 Mar 2021 19:52:37
User entered 'No (N)'	System	12 Mar 2021 19:52:37

**US3642268**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e52453da85ade033)', Time: '2021-03-12T11:52:35-08:00', User OID: 'PatientReportedOutcome (US3642268)', ODM File OID: 'ac35e2d8-e14f-432d-a068-5f055e83035e' User entered '12 Mar 2021 11:52:35'	System	12 Mar 2021 19:52:37
	System	12 Mar 2021 19:52:37

US3642268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	15 Dec 2020 19:36:37

**US3642268**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15 Dec 2020'	(b) (4) Lindsey Woronicz (b) (4)	15 Dec 2020 19:36:37



US3642268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	15 Dec 2020 19:36:37

US3642268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	15 Dec 2020 19:36:37

US3642268

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	15 Dec 2020 19:37:34

**US3642268**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:43:34
User entered 'I'	System	15 Dec 2020 19:37:34

**US3642268**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	20 Jan 2021 18:54:22

**US3642268**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '19 Jan 2021'	(b) (4) Lindsey Woronicz (b) (4)	20 Jan 2021 18:54:22

**US3642268**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	20 Jan 2021 18:54:22

**US3642268**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	20 Jan 2021 18:54:22



US3642268

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	20 Jan 2021 18:54:26

**US3642268**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User entered 'I'	System	20 Jan 2021 18:54:26

**US3642268**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	20 Feb 2021 17:17:22

US3642268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '19 Feb 2021'	(b) (4) Colleen McLellan (b) (4)	20 Feb 2021 17:17:22

US3642268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colleen McLellan (b) (4)	20 Feb 2021 17:17:22

US3642268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Colleen McLellan (b) (4)	20 Feb 2021 17:17:22

US3642268

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	20 Feb 2021 17:17:26

**US3642268**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User entered 'I'	System	20 Feb 2021 17:17:26



US3642268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:02:59
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	17 Mar 2021 16:36:53

US3642268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:02:59
User entered '17 Mar 2021'	Jennifer Morales (b) (4)	17 Mar 2021 16:36:53

US3642268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:02:59
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	17 Mar 2021 16:36:53

US3642268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:02:59
User entered empty.	Jennifer Morales (b) (4)	17 Mar 2021 16:36:53

US3642268

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:02:59
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4)	17 Mar 2021 16:37:00

**US3642268**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:32:36
User entered '1'	System	17 Mar 2021 16:37:00

**US3642268**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:37

US3642268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
	(b) (4)	
User entered '19 Apr 2021'	Son Do (b) (4)	20 Apr 2021 16:35:37



US3642268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:37

**US3642268**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 16:35:37

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered 'No (N)'	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

**US3642268**

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

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

**US3642268**

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

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45



US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

**US3642268**

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

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

**US3642268**

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

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:45



**US3642268**

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

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:27**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:35:45

US3642268

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered 'No (N)'	(b) (4) Son Do (b) (4)	20 Apr 2021 16:35:51

**US3642268**

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

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:27**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered empty.	Son Do (b) (4)	20 Apr 2021 16:35:51

US3642268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	20 Apr 2021 16:36:02

US3642268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered '19 Apr 2021'	(b) (4) Son Do (b) (4)	20 Apr 2021 16:36:02

US3642268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
User entered '15:30'	(b) (4) Son Do (b) (4)	20 Apr 2021 16:36:02

**US3642268**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 15:30'	System	20 Apr 2021 16:36:02

US3642268

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	20 Apr 2021 16:36:07



**US3642268**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 16:36:07

**US3642268**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	29 Jan 2021 17:35:27

US3642268

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

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '26 Jan 2021'	Son Do (b) (4)	29 Jan 2021 17:35:27

US3642268

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

Form: Visit Date

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Clinic (Clinic)'	Son Do (b) (4)	29 Jan 2021 17:35:27

**US3642268**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 17:35:27

US3642268

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '26 Jan 2021'	Son Do (b) (4)	29 Jan 2021 17:36:02

**US3642268**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:27**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:23:51
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:49:20

US3642268

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	29 Jan 2021 17:36:02



**US3642268**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:27**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:23:51
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:49:20

US3642268

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '26 Jan 2021'	Son Do (b) (4)	29 Jan 2021 17:36:02

US3642268

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'mRNA-1273 (mRNA-1273)'	Son Do (b) (4)	29 Jan 2021 17:36:02

US3642268

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'mRNA-1273 (mRNA-1273)'	Son Do (b) (4)	29 Jan 2021 17:36:02

**US3642268**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:27**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Not Administered (NA)'	Son Do (b) (4)	29 Jan 2021 17:36:02

US3642268

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'No (N)'	Son Do (b) (4)	29 Jan 2021 17:36:02

**US3642268**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:27**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered empty.	System	29 Jan 2021 17:36:02

**US3642268**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:27**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered empty.	System	29 Jan 2021 17:36:02



US3642268

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	29 Jan 2021 17:36:19

US3642268

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '26 Jan 2021'	Son Do (b) (4)	29 Jan 2021 17:36:19

US3642268

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15:47'	Son Do (b) (4)	29 Jan 2021 17:36:19

**US3642268**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '26 Jan 2021 15:47'	System	29 Jan 2021 17:36:19

US3642268

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:58:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)'	Son Do (b) (4)	29 Jan 2021 17:36:30

US3642268

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:58:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-JAN-2021 is recorded under Participant Decision Visit / OL-D1 visit in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-JAN-2021 is recorded under Participant Decision Visit / OL-D1 visit in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession Number: 1F60KGJ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 08:07:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-JAN-2021 is recorded under Participant Decision Visit / OL-D1 visit in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession Number: 1F60KGJ' (Site from DM).	Benjamin Hull (b) (4)	02 Mar 2021 18:35:06
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-JAN-2021 is recorded under Participant Decision Visit / OL-D1 visit in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:14:56
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '26 Jan 2021'	Son Do (b) (4)	29 Jan 2021 17:36:30

**US3642268**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:58:27**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered '15:53'	Son Do (b) (4)	29 Jan 2021 17:36:30

**US3642268**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:58:27**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:16:07
User entered '26 Jan 2021 15:53'	System	29 Jan 2021 17:36:30



US3642268

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:58:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:44:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Stephen Spector (b) (4)	06 Nov 2020 00:17:06
User entered 'No (N)'	Megan Loughran (b) (4)	24 Oct 2020 21:12:26

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and/or location (arms, legs, etc.). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:55:12
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 21:03:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 21:03:58
Data point term sent to Coder	System	01 Feb 2021 21:03:22
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	01 Feb 2021 21:02:55
User entered 'peripheral NEUROPATHY' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	01 Feb 2021 21:02:55
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and/or location (arms, legs, etc.). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'con med box checked. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	01 Feb 2021 21:02:35
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and/or location (arms, legs, etc.). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Jan 2021 10:26:03
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 18:35:52

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Nov 2020 18:35:52
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	14 Nov 2020 18:35:16
User entered 'neuropathy'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered 'No (N)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered 'No (N)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered 'No (N)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '21 Sep 2020'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. So please reconcile to record the best estimate time in 24-hour clock format (HH:MM)'. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:51:40
Query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. So please reconcile to record the best estimate time in 24-hour clock format (HH:MM)'. Thank you.' answered with 'This information was not collected from participant, so there is no information in chart to provide. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	23 Nov 2020 22:35:41
User opened query 'Per CDM: As per CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. So please reconcile to record the best estimate time in 24-hour clock format (HH:MM)'. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:12:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 07:11:53
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 18:34:38
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Nov 2020 18:34:24
User entered empty.	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 18:34:24



**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 18:34:24

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4)	23 Nov 2020 22:32:29
	(b) (4)	
User entered 'Yes (Y)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	23 Nov 2020 22:32:29
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Nov 2020 22:32:29
User entered '04 Nov 2020' reason for change: Data Entry Error	Megan Loughran (b) (4)	23 Nov 2020 22:32:29
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	20 Nov 2020 17:53:57
User entered empty.	System	
	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:51:47
Query 'Data is required. Please provide.' answered with 'data were not collected. ' (Site from System).	Megan Loughran (b) (4) (b) (4)	23 Nov 2020 22:35:58
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Nov 2020 22:32:29
User entered empty.	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 18:34:24

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 18:34:24

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered 'No (N)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

Death

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	



US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Feb 2021 21:12:58
User entered empty.	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 18:34:24

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered empty.	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered empty.	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered empty.	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	



US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Related (RELATED)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Megan Loughran (b) (4)	14 Nov 2020 18:34:24

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per CDM: Please consider to complete 'Dosing Discontinuation' page appropriately. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 05:30:51
Query 'Per CDM: Please consider to complete 'Dosing Discontinuation' page appropriately. Thank you' answered with 'form completed' (Site from DM).	Megan Loughran (b) (4) (b) (4)	23 Nov 2020 22:37:57
User opened query 'Per CDM: Please consider to complete 'Dosing Discontinuation' page appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:52:49
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 18:34:24

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

None

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:55:30
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'con me box checked' (Site from DM).	Megan Loughran (b) (4) (b) (4)	01 Feb 2021 21:02:43
User entered '0' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	01 Feb 2021 21:02:28
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 17:43:47
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Nov 2020 18:34:49
User entered '1' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 18:34:49
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Nov 2020 18:34:24
User entered '0'	Megan Loughran (b) (4) (b) (4)	14 Nov 2020 18:34:24

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Megan Loughran (b) (4)	01 Feb 2021 21:02:28
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered '0'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Nancy Tang (b) (4)	20 Nov 2020 17:53:57
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	



**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
	(b) (4)	
User entered empty.	Megan Loughran (b) (4)	14 Nov 2020 18:34:24
	(b) (4)	

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'PATIENT REPORTED LEFT SIDE PAIN IN LEG AND FOOT FOLLOWING INJECTION (INJECTION GIVEN IN LEFT ARM). PAIN IN LEG REPORTED WHEN LYING ON LEFT SIDE. WHEN PRESSING ON INJECTION SITE, PATIENT NOTICED NERVE PAIN SHOOTING DOWN LEG. BURNING, TINGLING, AND PAIN REPORTED IN LEG AND BOTH FEET, specifically on the soles of the feet. OCCURRED DAILY, THEN REDUCED TO EVERY OTHER DAY, THEN 2 TIMES PER WEEK. SYMPTOMS STARTED AFTER VACCINATION AND HAVE PERSISTED. SYMPTOMS INTERFERED WITH ABILITY TO EXERCISE FOR SEVERAL WEEKS FOLLOWING THE INJECTION. SYMPTOMS HAVE RESOLVED AS OF 04 NOV 2020 WITHOUT FURTHER SEQUELLAE.' reason for change: New Information	(b) (4) Megan Loughran (b) (4)	23 Nov 2020 22:39:30
User entered 'PATIENT REPORTED LEFT SIDE PAIN IN LEG AND FOOT FOLLOWING INJECTION (INJECTION GIVEN IN LEFT ARM). PAIN IN LEG REPORTED WHEN LYING ON LEFT SIDE. WHEN PRESSING ON INJECTION SITE, PATIENT NOTICED NERVE PAIN SHOOTING DOWN LEG. BURNING, TINGLING, AND PAIN REPORTED IN LEG AND BOTH FEET. OCCURRED DAILY, THEN REDUCED TO EVERY OTHER DAY, THEN 2 TIMES PER WEEK. SYMPTOMS STARTED AFTER VACCINATION AND HAVE PERSISTED. SYMPTOMS INTERFERED WITH ABILITY TO EXERCISE FOR SEVERAL WEEKS FOLLOWING THE INJECTION. symptoms have resolved as of 04 nov 2020 without further sequellae.' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	23 Nov 2020 22:32:29

US3642268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient reported left side pain in leg and foot following injection (injection given in left arm). Pain in leg reported when lying on left side. When pressing on injection site, patient noticed nerve pain shooting down leg. Burning, tingling, and pain reported in leg and both feet. Occurred daily, then reduced to every other day, then 2 times per week. Symptoms started after vaccination and have persisted. Symptoms interfered with ability to exercise for several weeks following the injection.'	Megan Loughran (b) (4)	14 Nov 2020 18:34:24

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 18:34:24

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 18:34:24

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of toe - version MedDRA\\23.0.	Coder Import (b) (4)	07 Jan 2021 12:32:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Jan 2021 12:32:40
Data point term sent to Coder	System	07 Jan 2021 04:14:26
User entered 'Laceration and dislocation of the right toe'	Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27



US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '01 Jan 2021'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User entered empty.	System	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
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) System	07 Jan 2021 04:13:45
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	07 Jan 2021 04:13:45
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	07 Jan 2021 04:13:27
User entered '01 Jan 2021'	Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27



**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User entered empty.	System	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27



**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27



**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is PAIN AT INJURY SITE (LEFT TOE). Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 06:44:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is PAIN AT INJURY SITE (LEFT TOE). Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' answered with 'the indication on conmed (advil) has been revised to match ae. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Feb 2021 16:50:53
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is PAIN AT INJURY SITE (LEFT TOE). Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 01:55:13
User entered 'I'	Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Nancy Tang (b) (4)	07 Jan 2021 04:13:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

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 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:13:27

US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per DM CLR: Narrative = THE TOE IS NOW REPAIRED. However, please confirm if a surgical repair was performed and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 06:43:41
Query 'Per DM CLR: Narrative = THE TOE IS NOW REPAIRED. However, please confirm if a surgical repair was performed and ensure that this is captured in the appropriate eCRF. ' answered with 'no surgery was performed. the narrative has been updated to reflect this. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Feb 2021 16:51:51
User entered 'SUBJECT REPORTS THAT HE HAD MEGAN LOUGHRAN TO GO TO THE ER ON 01JAN2021 TO GET HELP FOR A LACERATION?AND DISLOCATION OF HIS RIGHT TOE. HE STATES THAT HE ACCIDENTALLY STEPPED ON A SHARP DEVICE AT HOME CAUSING INJURY.THE TOE IS NOW REPAIRED (non-surgical repair) AND SUBJECT WILL CONTINUE TO REMAIN ON THE STUDY.'	Megan Loughran (b) (4) (b) (4)	18 Feb 2021 16:51:32
reason for change: Data Entry Error		
User opened query 'Per DM CLR: Narrative = THE TOE IS NOW REPAIRED. However, please confirm if a surgical repair was performed and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 01:55:08
User entered 'Subject reports that he had to go to the ER on 01Jan2021 to get help for a laceration?and dislocation of his right toe. He states that he accidentally stepped on a sharp device at home causing injury.The toe is now repaired and subject will continue to remain on the study.'	Nancy Tang (b) (4)	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User entered '0'	System	07 Jan 2021 04:13:27

**US3642268**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58
User entered '1'	System	07 Jan 2021 04:13:27



US3642268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:52:58

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:44:03
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:56:55
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'this information has been corrected - indication of pain at injection site updated for log line 1' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Feb 2021 17:41:44
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 12:21:59
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' canceled (Site from DM).		09 Feb 2021 03:33:47

US3642268

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

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

**Generated On: 11 Aug 2021 22:58:27**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever &gt; 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:19:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	20 Nov 2020 17:54:21
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:29:09

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 10:13:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 10:13:54
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:53:25
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4) (b) (4)	04 Mar 2021 19:34:31 04 Mar 2021 19:34:06
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 17:40:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 17:40:56
Data point term sent to Coder Coding entries removed.	System Megan Loughran (b) (4) (b) (4)	18 Feb 2021 17:40:35 18 Feb 2021 17:39:49
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 17:59:01

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Nov 2020 17:59:01
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	20 Nov 2020 17:58:29
User entered 'Ibuprofen'	Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User closed query 'Per CDM Re-Query: Please note that AE #01 is PERIPHERAL NEUROPATHY. Please clarify further the updates made. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:39:21
Query 'Per CDM Re-Query: Please note that AE #01 is PERIPHERAL NEUROPATHY. Please clarify further the updates made. Thank you' answered with 'ibuprofen taken as con med for AE log line 1 peripheral neuropathy ' (Site from DM).	Colleen McLellan (b) (4)	04 Mar 2021 19:34:32
User entered 'peripheral neuropathy' reason for change: Data Entry Error	Colleen McLellan (b) (4)	04 Mar 2021 19:34:06
User opened query 'Per CDM Re-Query: Please note that AE #01 is PERIPHERAL NEUROPATHY. Please clarify further the updates made. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:56:09
User closed query 'Per DM CLR: This Conmed is given for the AE# 01. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		19 Feb 2021 16:56:09
User entered 'pain at injection site' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Feb 2021 17:39:49
Query 'Per DM CLR: This Conmed is given for the AE# 01. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'ae report has been reconciled to reflect use of conmed.' (Site from DM).	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:30:14
User opened query 'Per DM CLR: This Conmed is given for the AE# 01. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:46:56
User entered 'Neuropathy'	Nancy Tang (b) (4)	20 Nov 2020 17:58:10

PRODUCTION RELEASE (v12.003  
EAB) (1725)

974 of 1055

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '200'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10



US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'mg (mg)'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	Megan Loughran (b) (4)	18 Feb 2021 17:33:56
User entered 'as needed (PRN)'	(b) (4)	
	Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Oral (ORAL)'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Megan Loughran (b) (4)	18 Feb 2021 17:41:17
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Megan Loughran (b) (4)	18 Feb 2021 17:33:56
User entered 'UN Oct 2020'	(b) (4)	
	Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '0'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10



**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Megan Loughran (b) (4)	18 Feb 2021 17:41:17
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Megan Loughran (b) (4)	18 Feb 2021 17:33:56
User entered 'UN Oct 2020'	(b) (4)	
	Nancy Tang (b) (4)	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 17:58:10

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User entered '2'	System	18 Feb 2021 17:33:56
User entered empty.	System	20 Nov 2020 17:58:10

US3642268

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User entered '1'	System	18 Feb 2021 17:33:56
User entered empty.	System	20 Nov 2020 17:58:10

US3642268

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:52
User entered '804 (804)'	System	18 Feb 2021 17:33:56
User entered empty.	System	20 Nov 2020 17:58:10

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Jan 2021 14:41:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 14:41:40
Data point term sent to Coder	System	07 Jan 2021 04:16:26
User entered 'Cefalexin'	Nancy Tang (b) (4) (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55



US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Infection of the toe'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '500'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'mg (mg)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'four times daily (QID)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Oral (ORAL)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55



US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '01 Jan 2021'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 19:19:09
User entered 'No (N)' reason for change: New Information		22 Apr 2021 19:19:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Yes (Y)'	Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:52:38
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:19:09
User entered '13 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	22 Apr 2021 19:19:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:15:55

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User entered '4'	System	07 Jan 2021 04:15:55

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User entered '1'	System	07 Jan 2021 04:15:55

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:12:56
User entered '804 (804)'	System	07 Jan 2021 04:15:55



US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 19:49:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 19:49:05
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:53:25
Data point term sent to Coder	System	18 Feb 2021 16:50:32
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	18 Feb 2021 16:50:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 14:52:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 14:52:40
Data point term sent to Coder	System	07 Jan 2021 04:17:27
User entered 'IBUPROFEN'	Nancy Tang (b) (4) (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'laceration and dislocation of right toe'	(b) (4)	
reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Feb 2021 16:50:26
User entered 'PAIN AT INJURY SITE (LEFT TOE)'	(b) (4)	
	Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '200'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'mg (mg)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'as needed (PRN)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03



**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Oral (ORAL)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '01 Jan 2021'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '0'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).		07 Apr 2021 10:48:23
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'Verified per source. Conmed was taken for AE 01Jan2021-02Jan2021 even though AE was resolved on 01Jan2021.' (Site from DM).	Nancy Tang (b) (4)	06 Apr 2021 19:02:38
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 02:48:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '02 Jan 2021'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	07 Jan 2021 04:17:03

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User entered empty.	System	07 Jan 2021 04:17:03



**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User entered empty.	System	07 Jan 2021 04:17:03

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:13:00
User entered empty.	System	07 Jan 2021 04:17:03

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 17:40:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 17:40:54
Data point term sent to Coder User entered 'ibuprofen'	System Megan Loughran (b) (4)	18 Feb 2021 17:39:34 18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'neuropathy'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '200'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'mg (mg)'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31



US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'as needed (PRN)'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'Oral (ORAL)'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered empty.	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'un Oct 2020'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered '0'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'un Oct 2020'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31



US3642268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:53:25
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	18 Feb 2021 17:39:31

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User entered empty.	System	18 Feb 2021 17:39:31

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User entered empty.	System	18 Feb 2021 17:39:31

**US3642268**

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:13
User entered empty.	System	18 Feb 2021 17:39:31

US3642268

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:58:27**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:32:15
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 15:29:03

**US3642268**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:58:27**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:12:26
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered '21 Oct 2020'	Megan Loughran (b) (4)	23 Nov 2020 22:37:40

US3642268

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:12:26
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:12:58
User entered 'AE (specify) (ADVERSE EVENT)'	Megan Loughran (b) (4)	23 Nov 2020 22:37:40

US3642268

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:12:26
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:23:51
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 10:42:48
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'UPDATED PER REQUEST' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	10 Mar 2021 13:13:37
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	10 Mar 2021 13:13:30
User entered 'AE # 1' reason for change: Per Query Resolution	Colleen McLellan (b) (4) (b) (4)	10 Mar 2021 13:13:30
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:10:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Feb 2021 21:12:58
User closed query 'Per CDM:Requery:Kindly consider to complete all forms for End of study.Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:15:12
Query 'Per CDM:Requery:Kindly consider to complete all forms for End of study.Thank you.' answered with 'This participant is remaining on study for follow-up. His IP dosing was discontinued due to an AE, but he remains on protocol for follow-up. Dicontinuation form not completed because subject is not off study. Please advise on how to proceed. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Feb 2021 17:05:42
User opened query 'Per CDM:Requery:Kindly consider to complete all forms for End of study.Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 03:53:32



US3642268

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:27

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider to provide only the AE log line number instead of AETERM and kindly complete the End of study/Study discontinuation form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 03:49:09
Query 'Per CDM: Please consider to provide only the AE log line number instead of AETERM and kindly complete the End of study/Study discontinuation form as appropriate. Thank you.' answered with 'AE LOG LINE 1 ' (Site from DM).	Colleen McLellan (b) (4)	04 Feb 2021 21:27:45
User entered 'AE LOG LINE 1' reason for change: Per Query Resolution	(b) (4)	04 Feb 2021 21:27:38
User opened query 'Per CDM: Please consider to provide only the AE log line number instead of AETERM and kindly complete the End of study/Study discontinuation form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:41:25
User entered 'neuropathy temporally associated with vaccine dose 1'	Megan Loughran (b) (4)	23 Nov 2020 22:37:40

US3642268

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:58:27

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:18
	(b) (4)	
User entered '30 Apr 2021'	Colleen McLellan (b) (4)	03 May 2021 16:57:21
	(b) (4)	

**US3642268**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:27**

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:18
User entered 'Protocol deviation (specify (PROTOCOL DEVIATION)'	(b) (4) Colleen McLellan (b) (4)	03 May 2021 16:57:21
	(b) (4)	

US3642268

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:27**

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:18
User entered 'PARTICIPANT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY THROUGH EUA'	Colleen McLellan (b) (4)	03 May 2021 16:57:21

**US3642268**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:27**

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:18
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	03 May 2021 16:57:21
	(b) (4)	

**US3642268**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:27**

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:18
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	03 May 2021 16:57:21
	(b) (4)	

US3642268

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:58:27

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:18
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	03 May 2021 16:57:21
	(b) (4)	

**US3642268**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:27**

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:18
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	03 May 2021 16:57:21
	(b) (4)	