

US3242370 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:48:10

All time stamps listed in this document are displayed in GMT



**US3242370**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:48:10**

[Participant ID](#)

US3242370

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



US3242370

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:48:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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



US3242370

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:48:10

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



US3242370

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:48:10

Date of Informed Consent ( <i>dd MMM yyyy</i> )	23 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



US3242370

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:48:10

Did the participant meet all eligibility criteria?

Yes ☒

No ☐



**US3242370**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:48:10**

---

Were any significant conditions reported?

Yes ☒

No ☐

---



US3242370

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:12 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:12
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	224 lb
BMI ( <i>xxx.x</i> )	31.30698 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)	



US3242370

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

**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**

UNEMPLOYEED, OUT IN  
COMMUNITY SEVERAL TIMES  
A WEEK

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

**No Risk Identified** False

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



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:48:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

What was the date of randomization? (dd MMM yyyy) 23 SEP 2020

What was the participant's randomization number? 115090

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 ☒



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:48:10**

Height	ND - Not Done
Weight	ND - Not Done



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

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)	23 SEP 2020
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:21
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

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)	23 SEP 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 11:40
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG



US3242370

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:10

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.*



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	23 SEP 2020
What was the treatment time? (00:00-23:59)	11:10 (24 HR)
Treatment Date and Time (derived)	23 SEP 2020 11:10
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR



US3242370

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:48:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	23 SEP 2020
Collection time ( <i>00:00-23:59</i> )	10:57 (24 HR)
Collection date and time (derived)	23 SEP 2020 10:57



US3242370

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:48:10

Collection date ( <i>dd MMM yyyy</i> )			23 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	23 SEP 2020 10:50
Nasopharyngeal Swab 2	No		



US3242370

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:48:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 23 SEP 2020 11:35

PC Open Date & Time 23 SEP 2020 11:30

PC Close Date & Time 23 SEP 2020 14:00



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	23 SEP 2020 16:07
PC Open Date & Time	23 SEP 2020 14:55
PC Close Date & Time	24 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:48:10

---

**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

24 SEP 2020 14:43

---

PC Open Date & Time

24 SEP 2020 12:00

---

PC Close Date & Time

25 SEP 2020 11:59

---



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:48:10

---

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:48:10

**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**

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



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:48:10

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**

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 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:48:10

**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 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:48:10

**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**

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 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

**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

23 SEP 2020 11:36

PC Open Date & Time

23 SEP 2020 11:30

PC Close Date & Time

23 SEP 2020 14:00



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

**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

23 SEP 2020 16:07

PC Open Date & Time

23 SEP 2020 14:55

PC Close Date & Time

24 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:48:10

**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

24 SEP 2020 13:46

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:48:10

**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

25 SEP 2020 12:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:48:10

**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 ☐

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



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:48:10

**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 ☐

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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:48:10

**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

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:48:10

**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 ☐

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

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

**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 ☐



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 11:37
PC Open Date & Time	23 SEP 2020 11:30
PC Close Date & Time	23 SEP 2020 14:00



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

**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 ☐



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 16:08
PC Open Date & Time	23 SEP 2020 14:55
PC Close Date & Time	24 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:48:10

**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 ☒



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:48:10

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:46
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:48:10

**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 ☒



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:48:10

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:48:10

**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 ☐



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:48:10

**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 ☐



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:48:10

**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 ☐



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:48:10

**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 ☐



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:10

Was Contact Attempted?

Yes ☒

No ☐

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

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

UNABLE TO REACH SUBJECT

*If Contact Not Made, please provide Comments*



US3242370

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:48:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3242370

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:10

Was Contact Attempted?

Yes ☒

No ☐

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

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3242370

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:48:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3242370**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:48:10**

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*



**US3242370**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:48:10**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3242370

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:48:10

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"/>



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3242370

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:48:10

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

AEID	USA-US067-2020-MRNA-1273-P30 1000005
Adverse event	WORSENING OF SCHIZOAFFECTIVE DISORDER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 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)	03 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	03 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102)

63 of 545



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input 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	



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

---

SUBJECT WAS ADMITTED TO  
RIVERWOODS BEHAVIORAL  
HEALTH SYSTEM AFTER BEING  
EVALUATED AT PIEDMONT  
FAYETTE HOSPITAL ER.  
MEDICAL RECORDS RECEIVED  
AND STATES SUBJECT HAS  
PREVIOUS DIAGNOSIS OF  
SCHIZOAFFECTIVE DISORDER  
WHICH WAS NOT DISCLOSED  
AT SCREENING. HE WAS  
ADMITTED DUE TO SUICIDAL  
IDEATION, HOMICIDAL  
THOUGHTS AND AGGRESSION  
TOWARDS HIS PARENTS AND  
PETS. MEDICAL RECORDS DO  
NOT INDICATE THE DATE OF  
PRIOR DIAGNOSIS OR  
MEDICATIONS SUBJECT IS ON  
AND PATIENT DENIES HAVING  
ANY PRESCRIPTIONS AND ANY  
DIAGNOSIS.

---

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

---



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:48:10

---

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

Yes ☒

No ☐

---

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

---



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

Name of Medication	PROZAC
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SCHIZOAFFECTIVE DISORDER
Dose per administration	20
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

Name of Medication	SEROQUEL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SCHIZOAFFECTIVE DISORDER
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

Name of Medication	DEPAKOTE DELAYED RELEASE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SCHIZOAFFECTIVE DISORDER
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

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



US3242370

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:48:10

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.



US3242370

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:48:10

Date of dosing discontinuation (dd MMM yyyy)

19 OCT 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☒

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

SAE #1



US3242370

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:48:10

Date of study discontinuation/completion (*dd MMM yyyy*) 19 OCT 2020

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☒

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by participant (specify) ☐

Other ☐

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

WORSENING OF SCHIZOAFFECTIVE DISORDER, SUBJECT IS UNSTABLE AND PI NOT WILLING TO UPSET SUBJECT OR PUT STAFF AT RISK

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 ☐



US3242370

Folder: SAE USA-US067-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:48:10

SAEID	USA-US067-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3



US3242370

Folder: SAE USA-US067-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:48:10

SAEID	USA-US067-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/OCT/2020 11:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3242370

Folder: SAE USA-US067-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:48:10

SAEID	USA-US067-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3242370

Folder: SAE USA-US067-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:48:10

SAEID	USA-US067-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 13:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3242370 (Prod: Clinical Research Atlanta - ERN-PPDS)



**US3242370**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:48:10**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:03:55
User entered 'US3242370'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:14:38



**US3242370**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:11



**US3242370**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:02
User entered '23 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:14:39



**US3242370**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:02
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:11



**US3242370**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	23 Sep 2020 15:07:11



US3242370

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:48:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:14:40



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '28'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '28'	System	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered 'Male (M)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '1'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



US3242370

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:48:10

If race is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:48:10**

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:11
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:29



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered '2020'	System	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Amendment 3 (3)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:41



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:14:39



**US3242370**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:48:10**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 15:07:47



**US3242370**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:18
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:47



**US3242370**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:48:10**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Oct 2020 00:49:32
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:07:59



US3242370

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:10

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 04:49:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 04:49:21
Data point term sent to Coder	System	10 Oct 2020 00:51:49
User entered 'Schizoeffective Disorder'	Donna Toepfer (b) (4)	10 Oct 2020 00:51:26



US3242370

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Donna Toepfer (b) (4)	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 00:51:26



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered '10:12'	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:12'	System	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered '71' in	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35
DataPoint set to visible.	System	23 Sep 2020 15:07:47



US3242370

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:10

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered '224' lb	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35
DataPoint set to visible.	System	23 Sep 2020 15:07:47



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
User entered '31.30698'	System	23 Sep 2020 15:08:35
DataPoint set to visible.	System	23 Sep 2020 15:07:47



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	23 Sep 2020 15:08:35
DataPoint set to visible.	System	23 Sep 2020 15:07:47



US3242370

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:10

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:25
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	23 Sep 2020 15:08:35



**US3242370**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:48:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 15:08:35



US3242370

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:10

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:08:43



**US3242370**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 15:08:43



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered 'unemployed, out in community several times a week'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered '1'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



US3242370

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:10

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:31
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:09:23



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:48
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:33



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:48
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:33



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:48
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:33



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:48:10**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	23 Sep 2020 15:09:33



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered '23 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:04:23



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered '115090'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:04:23



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:04:23



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:44



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:44



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:44



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:44



US3242370

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:10

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:44



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:43
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:44
DataPoint set to visible.	System	23 Sep 2020 15:07:41



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:48:10**

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	23 Sep 2020 16:48:19



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:48:10**

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:48:10

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:48:10**

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '23 Sep 2020'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '10:21'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:21'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '98.7' F	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered empty.	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '76'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '16'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '128'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '80'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 10:48:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:48:10

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:48:10

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Erynn McKinley (b) (4) (b) (4)	23 Sep 2020 16:48:19



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '23 Sep 2020'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '11:40'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:40'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '98.5' F	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered empty.	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '66'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '14'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '122'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:54
User entered '78'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:19
	(b) (4)	



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 16:48:19



US3242370

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:10

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:09:51



US3242370

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:09:51



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:01
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:01
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:20:34



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:48:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:01
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:01
User entered '11:10'	Donna Toepfer (b) (4)	23 Sep 2020 15:20:34



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:48:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:10'	System	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:01
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:01
User entered 'ONCE'	System	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 15:20:34



US3242370

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:48:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:39



US3242370

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:48:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:16
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:58:08
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'shipped 9/29/2020 fed ex 9069 0787 1257' (Site from DM).	Susan Jones (b) (4) (b) (4)	06 Oct 2020 19:59:51
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 18:38:13
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:39



US3242370

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:48:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:16
User entered '10:57'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:39



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:48:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:57'	System	23 Sep 2020 15:10:39



US3242370

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:48:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:34
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:53



US3242370

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:48:10

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:53



US3242370

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:48:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:53



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:34
User entered '10:50'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:53



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:50'	System	23 Sep 2020 15:10:53



US3242370

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:48:10

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:53



US3242370

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:48:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:34
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:53



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:48:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:03:34
User entered empty.	Donna Toepfer (b) (4)	23 Sep 2020 15:10:53



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:10:53



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:48:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:04:41
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Sep 2020 16:48:30



**US3242370**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:48:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:48:30



**US3242370**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:35:32', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '4cf6daec-a095-4e39-9102-e443148ec7e2'	System	23 Sep 2020 15:36:01
User entered 'Yes (Y)'	System	23 Sep 2020 15:36:01



**US3242370**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:35:46', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '4cf6daec-a095-4e39-9102-e443148ec7e2'	System	23 Sep 2020 15:36:01
User entered '98.5'	System	23 Sep 2020 15:36:01



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:35:51', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '4cf6daec-a095-4e39-9102-e443148ec7e2'	System	23 Sep 2020 15:36:01
User entered 'No (N)'	System	23 Sep 2020 15:36:01



**US3242370**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:35:56', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '4cf6daec-a095-4e39-9102-e443148ec7e2'	System	23 Sep 2020 15:36:01
User entered '23 Sep 2020 11:35'	System	23 Sep 2020 15:36:01



**US3242370**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:30'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:06:50', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'e99aa6bc-01d9-40d5-8cdc-2729d7efeb61'	System	23 Sep 2020 20:07:10
User entered 'Yes (Y)'	System	23 Sep 2020 20:07:10



**US3242370**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:06:56', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'e99aa6bc-01d9-40d5-8cdc-2729d7efeb61'	System	23 Sep 2020 20:07:10
User entered '98.4'	System	23 Sep 2020 20:07:10



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:00', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'e99aa6bc-01d9-40d5-8cdc-2729d7efeb61'	System	23 Sep 2020 20:07:10
User entered 'No (N)'	System	23 Sep 2020 20:07:10



**US3242370**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:07', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'e99aa6bc-01d9-40d5-8cdc-2729d7efeb61'	System	23 Sep 2020 20:07:10
User entered '23 Sep 2020 16:07'	System	23 Sep 2020 20:07:10



**US3242370**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:55'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 2'	System	23 Sep 2020 15:20:34



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T14:43:40', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '1916ebbe-4cd5-436c-bd82-299f4fa80750'	System	24 Sep 2020 18:43:57
User entered 'Yes (Y)'	System	24 Sep 2020 18:43:57



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T14:43:49', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '1916ebbe-4cd5-436c-bd82-299f4fa80750'	System	24 Sep 2020 18:43:57
User entered '98.3'	System	24 Sep 2020 18:43:57



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T14:43:53', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '1916ebbe-4cd5-436c-bd82-299f4fa80750'	System	24 Sep 2020 18:43:57
User entered 'No (N)'	System	24 Sep 2020 18:43:57



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T14:43:55', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '1916ebbe-4cd5-436c-bd82-299f4fa80750'	System	24 Sep 2020 18:43:57
User entered '24 Sep 2020 14:43'	System	24 Sep 2020 18:43:57



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 3'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:04:34', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b5113063-9e01-4cc6-a817-b318bcbe4078'	System	25 Sep 2020 16:05:59
User entered 'Yes (Y)'	System	25 Sep 2020 16:05:59



**US3242370**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:04:41', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b5113063-9e01-4cc6-a817-b318bcbe4078'	System	25 Sep 2020 16:05:59
User entered '98.2'	System	25 Sep 2020 16:05:59



US3242370

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:04:49', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b5113063-9e01-4cc6-a817-b318bcbe4078'	System	25 Sep 2020 16:05:59
User entered 'No (N)'	System	25 Sep 2020 16:05:59



**US3242370**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:04:52', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b5113063-9e01-4cc6-a817-b318bcbe4078'	System	25 Sep 2020 16:05:59
User entered '25 Sep 2020 12:04'	System	25 Sep 2020 16:05:59



**US3242370**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 4'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 5'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 6'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 7'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:20:34



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:14', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a6002b7d-5d58-4793-aa5d-4da400f335f1'	System	23 Sep 2020 15:36:38
User entered 'None (1)'	System	23 Sep 2020 15:36:38



**US3242370**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:20', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a6002b7d-5d58-4793-aa5d-4da400f335f1'	System	23 Sep 2020 15:36:38
User entered 'No (N)'	System	23 Sep 2020 15:36:38



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:24', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a6002b7d-5d58-4793-aa5d-4da400f335f1'	System	23 Sep 2020 15:36:38
User entered 'No (N)'	System	23 Sep 2020 15:36:38



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:32', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a6002b7d-5d58-4793-aa5d-4da400f335f1'	System	23 Sep 2020 15:36:38
User entered 'None (1)'	System	23 Sep 2020 15:36:38



**US3242370**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:34', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a6002b7d-5d58-4793-aa5d-4da400f335f1'	System	23 Sep 2020 15:36:38
User entered '23 Sep 2020 11:36'	System	23 Sep 2020 15:36:38



**US3242370**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:30'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:20:34



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:30', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a04102b4-5484-49e5-b1ae-dc7bcb35cb83'	System	23 Sep 2020 20:07:46
User entered 'None (1)'	System	23 Sep 2020 20:07:46



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:33', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a04102b4-5484-49e5-b1ae-dc7bcb35cb83'	System	23 Sep 2020 20:07:46
User entered 'No (N)'	System	23 Sep 2020 20:07:46



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:36', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a04102b4-5484-49e5-b1ae-dc7bcb35cb83'	System	23 Sep 2020 20:07:46
User entered 'No (N)'	System	23 Sep 2020 20:07:46



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:40', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a04102b4-5484-49e5-b1ae-dc7bcb35cb83'	System	23 Sep 2020 20:07:46
User entered 'None (1)'	System	23 Sep 2020 20:07:46



**US3242370**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:42', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a04102b4-5484-49e5-b1ae-dc7bcb35cb83'	System	23 Sep 2020 20:07:46
User entered '23 Sep 2020 16:07'	System	23 Sep 2020 20:07:46



**US3242370**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:55'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 2'	System	23 Sep 2020 15:20:34



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:15', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b95f2689-ee85-4d68-bc5f-d1b2a0882984'	System	24 Sep 2020 17:46:29
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 17:46:29



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:48:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:18', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b95f2689-ee85-4d68-bc5f-d1b2a0882984'	System	24 Sep 2020 17:46:29
User entered 'No (N)'	System	24 Sep 2020 17:46:29



**US3242370**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:21', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b95f2689-ee85-4d68-bc5f-d1b2a0882984'	System	24 Sep 2020 17:46:29
User entered 'No (N)'	System	24 Sep 2020 17:46:29



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:24', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b95f2689-ee85-4d68-bc5f-d1b2a0882984' User entered 'None (1)'	System	24 Sep 2020 17:46:29
	System	24 Sep 2020 17:46:29



**US3242370**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:27', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b95f2689-ee85-4d68-bc5f-d1b2a0882984'	System	24 Sep 2020 17:46:29
User entered '24 Sep 2020 13:46'	System	24 Sep 2020 17:46:29



**US3242370**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 3'	System	23 Sep 2020 15:20:34



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:34', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a0e0155e-310b-48b3-9370-e0ea89a76172'	System	25 Sep 2020 16:01:14
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 16:01:14



**US3242370**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:37', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a0e0155e-310b-48b3-9370-e0ea89a76172'	System	25 Sep 2020 16:01:14
User entered 'No (N)'	System	25 Sep 2020 16:01:14



**US3242370**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:40', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a0e0155e-310b-48b3-9370-e0ea89a76172'	System	25 Sep 2020 16:01:14
User entered 'No (N)'	System	25 Sep 2020 16:01:14



US3242370

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:48:10

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:43', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a0e0155e-310b-48b3-9370-e0ea89a76172'	System	25 Sep 2020 16:01:14
User entered 'None (1)'	System	25 Sep 2020 16:01:14



**US3242370**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:45', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'a0e0155e-310b-48b3-9370-e0ea89a76172'	System	25 Sep 2020 16:01:14
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 16:01:14



**US3242370**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 4'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 5'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 6'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 7'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:42', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c' User entered 'None (0)'	System	23 Sep 2020 15:37:07
	System	23 Sep 2020 15:37:07



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:45', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c' User entered 'None (0)'	System	23 Sep 2020 15:37:07
	System	23 Sep 2020 15:37:07



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:48', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c'	System	23 Sep 2020 15:37:07
User entered 'None (0)'	System	23 Sep 2020 15:37:07



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:51', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c'	System	23 Sep 2020 15:37:07
User entered 'None (0)'	System	23 Sep 2020 15:37:07



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:54', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c' User entered 'None (0)'	System	23 Sep 2020 15:37:07
	System	23 Sep 2020 15:37:07



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:36:57', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c' User entered 'None (0)'	System	23 Sep 2020 15:37:07
	System	23 Sep 2020 15:37:07



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:37:01', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c'	System	23 Sep 2020 15:37:07
User entered 'No (N)'	System	23 Sep 2020 15:37:07



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T11:37:03', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'b6e063b1-4bac-4245-b59f-9d1e73d2a34c' User entered '23 Sep 2020 11:37'	System	23 Sep 2020 15:37:07
	System	23 Sep 2020 15:37:07



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:30'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:48', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered 'None (0)'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:07:57', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered 'None (0)'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:08:00', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered 'None (0)'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:08:03', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered 'None (0)'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:08:06', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered 'None (0)'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:08:08', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered 'None (0)'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:08:11', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered 'No (N)'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-23T16:08:13', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '61006d07-6cf8-403d-80a9-fca7aee5dde4'	System	23 Sep 2020 20:08:46
User entered '23 Sep 2020 16:08'	System	23 Sep 2020 20:08:46



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:55'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 2'	System	23 Sep 2020 15:20:34



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:31', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8'	System	24 Sep 2020 17:46:53
User entered 'None (0)'	System	24 Sep 2020 17:46:53



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:34', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8'	System	24 Sep 2020 17:46:53
User entered 'None (0)'	System	24 Sep 2020 17:46:53



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:37', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8'	System	24 Sep 2020 17:46:53
User entered 'None (0)'	System	24 Sep 2020 17:46:53



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:39', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8'	System	24 Sep 2020 17:46:53
User entered 'None (0)'	System	24 Sep 2020 17:46:53



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:42', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8'	System	24 Sep 2020 17:46:53
User entered 'None (0)'	System	24 Sep 2020 17:46:53



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:44', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8'	System	24 Sep 2020 17:46:53
User entered 'None (0)'	System	24 Sep 2020 17:46:53



US3242370

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:47', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8'	System	24 Sep 2020 17:46:53
User entered 'No (N)'	System	24 Sep 2020 17:46:53



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-24T13:46:49', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: '175ea748-843b-4b1a-a6a6-78e2bdde01c8' User entered '24 Sep 2020 13:46'	System	24 Sep 2020 17:46:53
	System	24 Sep 2020 17:46:53



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

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

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 3'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:50', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc'	System	25 Sep 2020 16:01:48
User entered 'None (0)'	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:52', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc'	System	25 Sep 2020 16:01:48
User entered 'None (0)'	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:56', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc'	System	25 Sep 2020 16:01:48
User entered 'None (0)'	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:00:59', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc'	System	25 Sep 2020 16:01:48
User entered 'None (0)'	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:01:01', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc'	System	25 Sep 2020 16:01:48
User entered 'None (0)'	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:01:04', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc'	System	25 Sep 2020 16:01:48
User entered 'None (0)'	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:01:07', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc'	System	25 Sep 2020 16:01:48
User entered 'No (N)'	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49A8731C-0DEF-447D-A95D-233AF276A498)', Time: '2020-09-25T12:01:09', User OID: 'PatientReportedOutcome (US3242370)', ODM File OID: 'be83aa2e-8c24-432c-bced-f9f0bc0881fc' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 16:01:48
	System	25 Sep 2020 16:01:48



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 4'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 5'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 6'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 15:20:34
User entered 'Day 7'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:20:34



**US3242370**

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

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:48:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:20:34



US3242370

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:10

Was Contact Attempted?

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:16:41
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:15:59
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:15:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:15:59
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:14:50
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:14:50
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:14:50
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:14:38
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Oct 2020 13:10:25



US3242370

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:45:04
User entered '1 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:16:41
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 13:14:38
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Oct 2020 13:14:38
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:14:38
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 13:10:25
User entered '8 Oct 2020'	Erynn McKinley (b) (4)	08 Oct 2020 13:10:25



US3242370

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:15:04
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	08 Oct 2020 13:10:25



US3242370

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User closed query 'The Contact Status is 'CONTACT System NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).		08 Oct 2020 13:15:25
User entered 'Unable to reach subject' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:15:25
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:15:04
User entered empty.	Erynn McKinley (b) (4)	08 Oct 2020 13:10:25
	(b) (4)	



US3242370

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:48:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:15:50



**US3242370**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:48:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 13:15:50



**US3242370**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:48:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	08 Oct 2020 13:19:26



**US3242370**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:48:10**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:45:23
User entered '8 Oct 2020'	Erynn McKinley (b) (4)	08 Oct 2020 13:19:26
	(b) (4)	



US3242370

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	08 Oct 2020 13:19:26



**US3242370**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:48:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Oct 2020 13:19:26



US3242370

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:48:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	08 Oct 2020 13:19:30



**US3242370**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:48:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 13:19:30



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:48:10**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Oct 2020 00:49:14
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:04



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:08
User entered	System	12 Oct 2020 15:21:05
'USA-US067-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 15:21:05



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 05:01:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	10 Oct 2020 05:01:20
Data point term sent to Coder	System	10 Oct 2020 01:04:51
User entered 'WORSENING OF SCHIZOAffective disorder' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Oct 2020 01:04:41
User entered 'Worsening of Schizoaf'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '29 Sep 2020'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '03 Oct 2020'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'Grade 3/Severe (Grade 3/Severe)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '1'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '1'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '29 Sep 2020'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '03 Oct 2020'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 18:01:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 18:01:10
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'None (NONE)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		10 Oct 2020 01:04:56
User entered '0' reason for change: Data Entry Error Donna Toepfer	(b) (4)	10 Oct 2020 01:04:56
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	10 Oct 2020 01:04:02
User entered '1'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '1'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:42
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	20 Oct 2020 18:45:36
' (Site from Safety).		
User closed query 'PV Query: Were there any precipitating event(s) or triggers that may have led to the event (i.e. stressful event, treatment non-compliance, etc)? ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 18:45:24
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 18:45:05
User closed query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 18:44:52
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 18:44:22
Query 'PV Query: Were there any precipitating event(s) or triggers that may have led to the event (i.e. stressful event, treatment non-compliance, etc)? ' answered with 'unknown' (Site from Safety).	Donna Toepfer (b) (4)	19 Oct 2020 22:55:06
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'none' (Site from Safety).	Donna Toepfer (b) (4)	19 Oct 2020 22:55:01



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

[Narrative](#)

Audit	User	Time (GMT)
Query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none please state so. ' answered with 'none' (Site from Safety).	Donna Toepfer (b) (4)	19 Oct 2020 22:54:55
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so ' answered with 'none' (Site from Safety).	Donna Toepfer (b) (4)	19 Oct 2020 22:53:29
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.	Donna Toepfer (b) (4)	19 Oct 2020 22:53:22
' answered with 'updated' (Site from Safety). User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	15 Oct 2020 15:35:55
' (Site from Safety). User opened query 'PV Query: Were there any precipitating event(s) or triggers that may have led to the event (i.e. stressful event, treatment non-compliance, etc)? ' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:35:35
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:35:23
User opened query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:34:58



US3242370

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:48:10

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so ' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:34:43
User entered 'Subject was admitted to Riverwoods Behavioral Health System after being evaluated at Piedmont Fayette Hospital ER. Medical records received and states subject has previous diagnosis of Schizoaffective disorder which was not disclosed at screening. He was admitted due to suicidal ideation, homicidal thoughts and aggression towards his parents and pets. Medical records do not indicate the date of prior diagnosis or medications subject is on and patient denies having any prescriptions and any diagnosis.'	Donna Toepfer (b) (4)	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Oct 2020 01:04:02



**US3242370**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Oct 2020 01:04:02



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:48:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Oct 2020 01:05:16
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:09



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:47:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	10 Oct 2020 04:47:20
Data point term sent to Coder	System	10 Oct 2020 01:06:52
User entered 'Prozac'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Schizoaffective Disorder'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '20'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '1 Oct 2020'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 01:06:04



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 01:06:04



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 01:07:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 01:07:14
Data point term sent to Coder	System	10 Oct 2020 01:06:52
User entered 'Seroquel'	Donna Toepfer (b) (4)   	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Schizoaffective Disorder'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '50'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '1 Oct 2020'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 01:06:40



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 01:06:40



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:56:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:56:21
Data point term sent to Coder	System	10 Oct 2020 01:07:52
User entered 'Depakote Delayed Release'	Donna Toepfer (b) (4)   	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Schizoaffective Disorder'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '500'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '1 Oct 2020'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered '0'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered empty.	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 01:07:21



**US3242370**

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 01:07:21



US3242370

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:48:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:08
User entered 'No (N)'	Donna Toepfer (b) (4)	23 Sep 2020 15:10:15



**US3242370**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 10:48:10**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:17
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	19 Oct 2020 17:50:35



US3242370

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:48:10

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CD: SAE recorded as Dosing Discontinuation, however: it is not recorded as IP withdrawal, please reconcile. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:23:08
Query 'Per CD: SAE recorded as Dosing Discontinuation, however: it is not recorded as IP withdrawal, please reconcile. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 18:01:48
User opened query 'Per CD: SAE recorded as Dosing Discontinuation, however: it is not recorded as IP withdrawal, please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 19:56:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:17
User entered 'SAE (specify) (SAE)'	Donna Toepfer (b) (4)	19 Oct 2020 17:50:35



US3242370

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:48:10

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 record SAE record number instead of details' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:48:57
Query 'Per CDM: please record SAE record number instead of details' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	18 Nov 2020 14:52:15
DataPoint Un-verified.	Donna Toepfer (b) (4)	18 Nov 2020 14:52:11
User entered 'SAE #1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Nov 2020 14:52:11
User opened query 'Per CDM: please record SAE record number instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:49:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:17
User entered 'Worsening of Schizoaffective Disorder'	Donna Toepfer (b) (4)	19 Oct 2020 17:50:35



US3242370

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:48:10

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: SAE and Adverse Events have same date, however, consider updating End Of Study form to SAE, this does not match Dosing Discontinuation page.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:22:40
Query 'Per CDM: SAE and Adverse Events have same date, however, consider updating End Of Study form to SAE, this does not match Dosing Discontinuation page.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 18:02:29
User opened query 'Per CDM: SAE and Adverse Events have same date, however, consider updating End Of Study form to SAE, this does not match Dosing Discontinuation page.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 19:53:10
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:25
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	19 Oct 2020 17:54:50



US3242370

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:48:10

[Reason for discontinuation](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 18:02:24
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 18:02:24
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:25
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Donna Toepfer (b) (4)	19 Oct 2020 17:54:50



US3242370

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:48:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:25
User entered 'Worsening of Schizoaffective Disorder, subject is unstable and PI not willing to upset subject or put staff at risk'	Donna Toepfer (b) (4)	19 Oct 2020 17:54:50



**US3242370**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 26 Nov 2020 10:48:10**

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:25
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 17:54:50



**US3242370**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 26 Nov 2020 10:48:10**

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:25
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 17:54:50



**US3242370**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 26 Nov 2020 10:48:10**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:25
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 17:54:50



**US3242370**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 26 Nov 2020 10:48:10**

[Was autopsy performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:06:25
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 17:54:50



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'USA-US067-2020-MRNA-1273-P301000005'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:15:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered 'US'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 13:15:37
User entered '2'	System	20 Oct 2020 18:27:29
User entered '1'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'USA-US067-2020-MRNA-1273-P301000005'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:15:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered 'US'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 13:15:37
User entered '2'	System	20 Oct 2020 18:27:29
User entered '1'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:48:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered '12/Oct/2020 11:21'	System	12 Oct 2020 15:21:25



US3242370

Folder: SAE USA-US067-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:48:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:15:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'USA-US067-2020-MRNA-1273-P301000005'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:15:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered 'US'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 13:15:37
User entered '2'	System	20 Oct 2020 18:27:29
User entered '1'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:48:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered '20/Oct/2020 14:27'	System	20 Oct 2020 18:27:29



US3242370

Folder: SAE USA-US067-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:48:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:15:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 18:27:29



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'USA-US067-2020-MRNA-1273-P301000005'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'Yes (Y)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:21:19
User entered 'No (N)'	System	12 Oct 2020 15:21:05



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:15:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:05:27
User entered 'US'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:48:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 13:15:37
User entered '2'	System	20 Oct 2020 18:27:29
User entered '1'	System	12 Oct 2020 15:21:25



**US3242370**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:48:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 13:15'	System	24 Nov 2020 13:15:37



US3242370

Folder: SAE USA-US067-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:48:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 13:15:37