

US3002046 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:48:58

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US3002046

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

[Participant ID](#)

US3002046

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

US3002046

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 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

US3002046

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Date of Informed Consent (<i>dd MMM yyyy</i>)	29 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 12:50:15

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:26
Height (xxx.x)	167 cm
Weight (xxx.x)	88.1 kg
BMI (xxx.x)	31.58952 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Date of assessment (*dd MMM yyyy*) 29 JUL 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:50:15

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 100184

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 12:50:17

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

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)	29 JUL 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:26
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

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)	29 JUL 2020
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 15:12
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:50:15

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Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 JUL 2020

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 14:40

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JUL 2020

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

29 JUL 2020 14:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:46	29 JUL 2020 13:46
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

98.4 °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

29 JUL 2020 15:10

PC Open Date & Time

29 JUL 2020 15:00

PC Close Date & Time

29 JUL 2020 17:30

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	29 JUL 2020 18:25
PC Open Date & Time	29 JUL 2020 18:25
PC Close Date & Time	30 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

30 JUL 2020 13:21

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 12:04

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 12:01

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 17:44

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 12:02

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

04 AUG 2020 12:23

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 15:11

PC Open Date & Time

29 JUL 2020 15:00

PC Close Date & Time

29 JUL 2020 17:30

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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

29 JUL 2020 18:26

PC Open Date & Time

29 JUL 2020 18:25

PC Close Date & Time

30 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

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

30 JUL 2020 13:22

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

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

31 JUL 2020 12:04

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 12:01

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 17:44

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 12:02

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 12:24

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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 ☐

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 15:11
PC Open Date & Time	29 JUL 2020 15:00
PC Close Date & Time	29 JUL 2020 17:30

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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 ☐

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 18:26
PC Open Date & Time	29 JUL 2020 18:25
PC Close Date & Time	30 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 13:22
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 12:05
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

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

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 17:44
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

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

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 12:24
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002046

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002046

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002046

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID VISIT2

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

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

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

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

US3002046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

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.

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3002046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:50:17

Generated On: 09 Jun 2021 14:48:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

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

US3002046

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

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

US3002046

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:50:15

Generated On: 09 Jun 2021 14:48:58

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 OCT 2020 17:54:35

Patient Cloud Open Date & Time

28 SEP 2020 00:01

Patient Cloud Close Date & Time

02 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 17:43:42

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 10:18:53

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 13:57:20
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 10:39:27

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3002046

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:48:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3002046

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:48:58

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"/>

US3002046

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:48:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3002046

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

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3002046

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

Form: Unblinding

Generated On: 09 Jun 2021 14:48:58

Date of updated informed consent (*dd MMM yyyy*)

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

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3002046

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3002046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:58

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3002046

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

AEID	USA-US005-2020-MRNA-1273-P30 1000001
Adverse event	LEFT HIP FRACTURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 AUG 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)	14 AUG 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	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT. WAS WALKING HER DOG AND TRIPPED AND BROKE HER LEFT HIP. PATIENT WENT TO BERGAN MERCY ER AND HAD SURGERY. MEDICAL RECORDS ARE PENDING.
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

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

US3002046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

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

Yes ☐

No ☒

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

US3002046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3002046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 AUG 2020	LEFT HIP FRACTURE REPAIR	Adverse Event	

US3002046

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 01 May 2021 11:48:47

Generated On: 09 Jun 2021 14:48:58

Date of dosing discontinuation (dd MMM yyyy)	06 NOV 2020
--	-------------

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1
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US3002046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 01 May 2021 11:48:47

Generated On: 09 Jun 2021 14:48:58

Date of study discontinuation/completion (dd MMM yyyy) 06 NOV 2020

Reason for discontinuation

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

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

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	07/SEP/2020 13:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/SEP/2020 09:07
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	13/NOV/2020 10:43
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	21/NOV/2020 02:12
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/NOV/2020 14:38
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/NOV/2020 20:49
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	04/JAN/2021 17:12
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 13 Feb 2021 12:50:14

Generated On: 09 Jun 2021 14:48:58

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/FEB/2021 14:10
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.	True

Audit

US3002046 (Prod: Meridian Clinical Research)

US3002046

Form: Participant Creation

Generated On: 09 Jun 2021 14:48:58

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'US3002046'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:54:57

US3002046

Form: Participant Creation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:34:16

US3002046

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:54:58

US3002046

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:34:16

US3002046

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'SCRN'	System	30 Jul 2020 14:34:16

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:54:59

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '60'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'YEARS'	System	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered '60'	System	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'I'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4)	30 Jul 2020 14:34:33
	(b) (4), (b) (6)	

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	Jessica Satorie (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'Jul 2020'	System	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered '2020'	System	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Amendment 1 (1)'	Jessica Satorie (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Jessica Satorie (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Jessica Satorie (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	Jessica Satorie (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:54:58

US3002046

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'I'	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:48:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 16:00:41
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:34:57

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:27:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:27:35
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:03:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:03:05
Data point term sent to Coder	System	14 Sep 2020 16:02:10
User entered 'post- menopausal'	(b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'Jan 2010'	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered '2010'	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '13:26'	(b) (4)	30 Jul 2020 14:36:04
	(b) (4), (b) (6)	

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered '29 Jul 2020 13:26'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '167' cm	(b) (4)	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
Amendment Manager: User entered '31.58952'	System	16 Sep 2020 23:38:20
User entered '31.6'	System	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'kg/m2'	System	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered '37.0' C	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered missing code ND - Not Done; reason for	(b) (4)	02 Sep 2020 17:16:50
change Data Entry Error	(b) (4), (b) (6)	
User entered '81'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'bpm'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 17:16:50
User entered '16'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'breaths/min'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 17:16:50
User entered '126'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'mmHg'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered '76'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'mmHg'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41

US3002046

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:36:15

US3002046

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:36:15

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 03:00:58
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'will update MH' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:00:24
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 10:09:26
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'un UNK 2010'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:58

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Aug 2020 16:51:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 16:51:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Aug 2020 16:51:02
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Jul 2020 14:35:22
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'I'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'Yes (Y)'	(b) (4)	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'VISIT1'	System	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:20:51

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:16:50
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:16:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 19:20:51
User entered '100184' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:20:51

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:20:51

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4)	30 Jul 2020 14:37:11
	(b) (4), (b) (6)	

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '167' cm	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered missing code ND - Not Done; reason for	(b) (4)	02 Sep 2020 17:18:28
change Data Entry Error	(b) (4), (b) (6)	
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered missing code ND - Not Done; reason for	(b) (4)	02 Sep 2020 17:18:28
change Data Entry Error	(b) (4), (b) (6)	
User entered '167' cm	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '13:26'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered '29 Jul 2020 13:26'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '37.0' C	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '81'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'bpm'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '16'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'breaths/min'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '126'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '76'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '167' cm	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4)	04 Aug 2020 16:06:39
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	30 Jul 2020 14:38:19
User entered '15:12'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered '29 Jul 2020 15:12'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '36.9' C	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '64'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'bpm'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '14'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'breaths/min'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '120'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered '83'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:38:31

US3002046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:31

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Jessica Satorie (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Jessica Satorie (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	Jessica Satorie (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '14:40'	Jessica Satorie (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered '29 Jul 2020 14:40'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'ONCE'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '14:05'	(b) (4), (b) (6)	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered '29 Jul 2020 14:05'	System	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:48:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '13:46'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered '29 Jul 2020 13:46'	System	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 14:40:29

US3002046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'I'	System	30 Jul 2020 14:40:29

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:09:40', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913' User entered 'Yes (Y)'	System	29 Jul 2020 20:10:04
	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:09:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913' User entered '98.4'	System	29 Jul 2020 20:10:04
	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:09:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913'	System	29 Jul 2020 20:10:04
User entered 'No (N)'	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:10:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913' User entered '29 Jul 2020 15:10'	System	29 Jul 2020 20:10:04
	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 15:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 17:30'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:31', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808' User entered 'Yes (Y)'	System	29 Jul 2020 23:25:53
	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:39', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808' User entered '97.7'	System	29 Jul 2020 23:25:53
	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:43', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808' User entered 'No (N)'	System	29 Jul 2020 23:25:53
	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808' User entered '29 Jul 2020 18:25'	System	29 Jul 2020 23:25:53
	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 18:25'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 2'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05' User entered 'Yes (Y)'	System	30 Jul 2020 18:21:57
	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05' User entered '97.3'	System	30 Jul 2020 18:21:57
	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:52', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05' User entered 'No (N)'	System	30 Jul 2020 18:21:57
	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05' User entered '30 Jul 2020 13:21'	System	30 Jul 2020 18:21:57
	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 3'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7' User entered 'Yes (Y)'	System	31 Jul 2020 17:04:38
	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7' User entered '98.5'	System	31 Jul 2020 17:04:38
	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:31', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7' User entered 'No (N)'	System	31 Jul 2020 17:04:38
	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:37', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7' User entered '31 Jul 2020 12:04'	System	31 Jul 2020 17:04:38
	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 4'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:04', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82'	System	01 Aug 2020 17:01:37
User entered 'Yes (Y)'	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82' User entered '97.8'	System	01 Aug 2020 17:01:37
	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:32', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82'	System	01 Aug 2020 17:01:37
User entered 'No (N)'	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82' User entered '01 Aug 2020 12:01'	System	01 Aug 2020 17:01:37
	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 5'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:01', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c' User entered 'Yes (Y)'	System	02 Aug 2020 22:44:17
	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:06', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c' User entered '97.8'	System	02 Aug 2020 22:44:17
	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c'	System	02 Aug 2020 22:44:17
User entered 'No (N)'	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c' User entered '02 Aug 2020 17:44'	System	02 Aug 2020 22:44:17
	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 6'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:01:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f' User entered 'Yes (Y)'	System	03 Aug 2020 17:02:03
	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:01:54', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f' User entered '98.1'	System	03 Aug 2020 17:02:03
	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:01:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f'	System	03 Aug 2020 17:02:03
User entered 'No (N)'	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f' User entered '03 Aug 2020 12:02'	System	03 Aug 2020 17:02:03
	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 7'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150facal' User entered 'Yes (Y)'	System	04 Aug 2020 17:23:49
	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:33', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150facal' User entered '97.5'	System	04 Aug 2020 17:23:49
	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150facal' User entered 'No (N)'	System	04 Aug 2020 17:23:49
	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:48', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150faca1' User entered '04 Aug 2020 12:23'	System	04 Aug 2020 17:23:49
	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:10:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1' User entered 'None (1)'	System	29 Jul 2020 20:11:12
	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:10:57', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1' User entered 'No (N)'	System	29 Jul 2020 20:11:12
	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1' User entered 'No (N)'	System	29 Jul 2020 20:11:12
	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1' User entered 'None (1)'	System	29 Jul 2020 20:11:12
	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1' User entered '29 Jul 2020 15:11'	System	29 Jul 2020 20:11:12
	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 15:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 17:30'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8'	System	29 Jul 2020 23:26:07
User entered 'None (1)'	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:56', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8' User entered 'No (N)'	System	29 Jul 2020 23:26:07
	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8' User entered 'No (N)'	System	29 Jul 2020 23:26:07
	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8'	System	29 Jul 2020 23:26:07
User entered 'None (1)'	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8' User entered '29 Jul 2020 18:26'	System	29 Jul 2020 23:26:07
	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 18:25'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 2'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'None (1)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'No (N)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:08', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'No (N)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:13', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'None (1)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:16', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64' User entered '30 Jul 2020 13:22'	System	30 Jul 2020 18:22:18
	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 3'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f' User entered 'None (1)'	System	31 Jul 2020 17:04:56
	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f' User entered 'No (N)'	System	31 Jul 2020 17:04:56
	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f' User entered 'No (N)'	System	31 Jul 2020 17:04:56
	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:51', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f' User entered 'None (1)'	System	31 Jul 2020 17:04:56
	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:54', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f' User entered '31 Jul 2020 12:04'	System	31 Jul 2020 17:04:56
	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 4'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:39', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8'	System	01 Aug 2020 17:01:50
User entered 'None (1)'	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8' User entered 'No (N)'	System	01 Aug 2020 17:01:50
	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8' User entered 'No (N)'	System	01 Aug 2020 17:01:50
	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8'	System	01 Aug 2020 17:01:50
User entered 'None (1)'	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8' User entered '01 Aug 2020 12:01'	System	01 Aug 2020 17:01:50
	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 5'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:20', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered 'None (1)'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered 'No (N)'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:26', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5' User entered 'No (N)'	System	02 Aug 2020 22:44:36
	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:30', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered 'None (1)'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:33', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5' User entered '02 Aug 2020 17:44'	System	02 Aug 2020 22:44:36
	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 6'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d'	System	03 Aug 2020 17:02:52
User entered 'None (1)'	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:32', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d' User entered 'No (N)'	System	03 Aug 2020 17:02:52
	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:38', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d' User entered 'No (N)'	System	03 Aug 2020 17:02:52
	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d'	System	03 Aug 2020 17:02:52
User entered 'None (1)'	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:51', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d' User entered '03 Aug 2020 12:02'	System	03 Aug 2020 17:02:52
	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 7'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:52', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de' User entered 'None (1)'	System	04 Aug 2020 17:24:05
	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de' User entered 'No (N)'	System	04 Aug 2020 17:24:05
	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:57', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de'	System	04 Aug 2020 17:24:05
User entered 'No (N)'	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de'	System	04 Aug 2020 17:24:05
User entered 'None (1)'	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:03', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de' User entered '04 Aug 2020 12:24'	System	04 Aug 2020 17:24:05
	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered 'None (0)'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:17', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered 'None (0)'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:20', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered 'None (0)'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:22', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered 'None (0)'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered 'None (0)'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered 'None (0)'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:32', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered 'No (N)'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f' User entered '29 Jul 2020 15:11'	System	29 Jul 2020 20:11:37
	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 15:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 17:30'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'None (0)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:11', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'None (0)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:14', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'None (0)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:17', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'None (0)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'None (0)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'None (0)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'No (N)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered '29 Jul 2020 18:26'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '29 Jul 2020 18:25'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 2'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered 'None (0)'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered 'None (0)'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:28', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered 'None (0)'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:31', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered 'None (0)'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:34', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered 'None (0)'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:44', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered 'None (0)'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:48', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered 'No (N)'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:51', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a' User entered '30 Jul 2020 13:22'	System	30 Jul 2020 18:22:52
	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 3'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered 'None (0)'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:01', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered 'None (0)'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:04', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered 'None (0)'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered 'None (0)'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:11', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered 'None (0)'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:14', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered 'None (0)'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:18', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered 'No (N)'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered '31 Jul 2020 12:05'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 4'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40' User entered 'None (0)'	System	01 Aug 2020 17:02:10
	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40' User entered 'None (0)'	System	01 Aug 2020 17:02:10
	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:56', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40' User entered 'None (0)'	System	01 Aug 2020 17:02:10
	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40' User entered 'None (0)'	System	01 Aug 2020 17:02:10
	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40' User entered 'None (0)'	System	01 Aug 2020 17:02:10
	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40' User entered 'None (0)'	System	01 Aug 2020 17:02:10
	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'No (N)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:08', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40' User entered '01 Aug 2020 12:02'	System	01 Aug 2020 17:02:10
	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 5'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:38', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104' User entered 'None (0)'	System	02 Aug 2020 22:44:59
	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:40', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104' User entered 'None (0)'	System	02 Aug 2020 22:44:59
	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104' User entered 'None (0)'	System	02 Aug 2020 22:44:59
	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104' User entered 'None (0)'	System	02 Aug 2020 22:44:59
	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'No (N)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104' User entered '02 Aug 2020 17:44'	System	02 Aug 2020 22:44:59
	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 6'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:56', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0' User entered 'None (0)'	System	03 Aug 2020 17:03:18
	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0' User entered 'None (0)'	System	03 Aug 2020 17:03:18
	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0' User entered 'None (0)'	System	03 Aug 2020 17:03:18
	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0' User entered 'None (0)'	System	03 Aug 2020 17:03:18
	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:04', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0' User entered 'None (0)'	System	03 Aug 2020 17:03:18
	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:06', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0' User entered 'None (0)'	System	03 Aug 2020 17:03:18
	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:10', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'No (N)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:16', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0' User entered '03 Aug 2020 12:03'	System	03 Aug 2020 17:03:18
	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 7'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:07', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:11', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0' User entered 'None (0)'	System	04 Aug 2020 17:24:29
	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:13', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0' User entered 'None (0)'	System	04 Aug 2020 17:24:29
	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:22', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'No (N)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered '04 Aug 2020 12:24'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '05 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:57:42

US3002046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'I'	System	06 Aug 2020 14:57:42

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
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).	(b) (4)	30 Sep 2020 16:58:50
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	14 Sep 2020 16:04:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	30 Sep 2020 16:58:50
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:04:16

US3002046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'I'	System	14 Sep 2020 16:04:16

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:04:35

US3002046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'I'	System	14 Sep 2020 16:04:35

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User closed query 'Per CDM: Please complete the rest of the forms in the Visit 2 Day 29 folder as these should not remain empty. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 08:10:08
Query 'Per CDM: Please complete the rest of the forms in the Visit 2 Day 29 folder as these should not remain empty. Thank you. ' answered with 'Subject withdrew consent and did not complete visit. Unable to answer past stating NO to was visit performed' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:20:42
User opened query 'Per CDM: Please complete the rest of the forms in the Visit 2 Day 29 folder as these should not remain empty. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:58:58
User entered 'No (N)'	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'VISIT2'	System	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4)	19 Nov 2020 17:30:57
	(b) (4), (b) (6)	

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4)	19 Nov 2020 17:30:57
	(b) (4), (b) (6)	

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4)	19 Nov 2020 17:30:57
	(b) (4), (b) (6)	

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4)	19 Nov 2020 17:30:57
	(b) (4), (b) (6)	

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:02

US3002046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:31:02

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	23 Nov 2020 23:53:22
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Nov 2020 23:53:22
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	19 Nov 2020 17:32:18
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:48:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered empty.	System	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:17
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:17:34

US3002046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:41
User entered 'I'	System	22 Sep 2020 03:17:34

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:24

US3002046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'I'	System	22 Sep 2020 03:18:24

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:33:03
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:38

US3002046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered empty.	System	19 Nov 2020 17:33:03
User entered 'I'	System	22 Sep 2020 03:18:38

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 64'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-02T17:54:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b2c9bda6-c641-461e-ba2e-7366be6c861a' User entered 'No (N)'	System	02 Oct 2020 22:54:37
	System	02 Oct 2020 22:54:37

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-02T17:54:26', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b2c9bda6-c641-461e-ba2e-7366be6c861a'	System	02 Oct 2020 22:54:37
User entered 'No (N)'	System	02 Oct 2020 22:54:37

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-02T17:54:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b2c9bda6-c641-461e-ba2e-7366be6c861a' User entered '02 Oct 2020 17:54:35'	System	02 Oct 2020 22:54:37
	System	02 Oct 2020 22:54:37

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 71'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-06T17:43:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8b176bc9-9a2a-416e-97fe-e7d035bc6917'	System	06 Oct 2020 22:43:45
User entered 'No (N)'	System	06 Oct 2020 22:43:45

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-06T17:43:39', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8b176bc9-9a2a-416e-97fe-e7d035bc6917'	System	06 Oct 2020 22:43:45
User entered 'No (N)'	System	06 Oct 2020 22:43:45

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-06T17:43:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8b176bc9-9a2a-416e-97fe-e7d035bc6917' User entered '06 Oct 2020 17:43:42'	System	06 Oct 2020 22:43:45
	System	06 Oct 2020 22:43:45

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 78'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-16T10:18:44', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '1b4b0afe-3fd6-4649-8007-08ebc602361f' User entered 'No (N)'	System	16 Oct 2020 15:18:59
	System	16 Oct 2020 15:18:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-16T10:18:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '1b4b0afe-3fd6-4649-8007-08ebc602361f' User entered 'No (N)'	System	16 Oct 2020 15:18:59
	System	16 Oct 2020 15:18:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-16T10:18:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '1b4b0afe-3fd6-4649-8007-08ebc602361f' User entered '16 Oct 2020 10:18:53'	System	16 Oct 2020 15:18:59
	System	16 Oct 2020 15:18:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 92'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-26T13:57:08', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '641b2b04-31f9-4041-a66e-610e915368a7' User entered 'No (N)'	System	26 Oct 2020 18:57:22
	System	26 Oct 2020 18:57:22

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-26T13:57:12', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '641b2b04-31f9-4041-a66e-610e915368a7' User entered 'No (N)'	System	26 Oct 2020 18:57:22
	System	26 Oct 2020 18:57:22

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-26T13:57:20', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '641b2b04-31f9-4041-a66e-610e915368a7' User entered '26 Oct 2020 13:57:20'	System	26 Oct 2020 18:57:22
	System	26 Oct 2020 18:57:22

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 99'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-11-02T10:39:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b10b74e2-6bc2-4d89-aa0a-4147cfeda05c' User entered 'No (N)'	System	02 Nov 2020 16:39:30
	System	02 Nov 2020 16:39:30

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-11-02T10:39:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b10b74e2-6bc2-4d89-aa0a-4147cfeda05c'	System	02 Nov 2020 16:39:30
User entered 'No (N)'	System	02 Nov 2020 16:39:30

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-11-02T10:39:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b10b74e2-6bc2-4d89-aa0a-4147cfeda05c' User entered '02 Nov 2020 10:39:27'	System	02 Nov 2020 16:39:30
	System	02 Nov 2020 16:39:30

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:20:16
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:48:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per CDM: Per Dosing discontinuation form the reason for discontinuation is SAE #1; however, on the SAE #1 page Action taken with Investigational product is not IP withdrawn. Kindly review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 06:26:57
Query 'Per CDM: Per Dosing discontinuation form the reason for discontinuation is SAE #1; however, on the SAE #1 page Action taken with Investigational product is not IP withdrawn. Kindly review and update as appropriate.' answered with 'data has been updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:26:29
User opened query 'Per CDM: Per Dosing discontinuation form the reason for discontinuation is SAE #1; however, on the SAE #1 page Action taken with Investigational product is not IP withdrawn. Kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 09:18:17
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	03 Sep 2020 16:54:42
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:18:44

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:05:43
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 17:05:11

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:24:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 16:56:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 16:56:25
Data point term sent to Coder	System	25 Nov 2020 16:55:31
DataPoint Un-verified.	Brandon Essink (b) (4) (b) (4)	25 Nov 2020 16:55:26
Coding entries removed.	Brandon Essink (b) (4) (b) (4)	25 Nov 2020 16:55:26
User entered 'LEFT HIP fracture' reason for change:	Brandon Essink (b) (4)	25 Nov 2020 16:55:26
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Broken hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 23:31:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 23:31:46
Data point term sent to Coder	System	03 Sep 2020 17:06:05
User entered 'Left Broken Hip'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'No (N)'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'No (N)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '12 Aug 2020'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered empty.	System	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:24:22
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 15:39:50
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:39:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:39:50
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 15:39:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:24:22
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 15:39:33
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Nov 2020 15:39:33
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:39:33
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:39:33
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 15:39:05
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
Query 'PV query: Please provide the stop date, when available. Please do not response to this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 17:21:50
User opened query 'PV query: Please provide the stop date, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:00:38
User entered empty.	System	03 Sep 2020 17:05:13

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Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:23:15
User closed query 'PV query: Please provide Grade/Severity for the event.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:06:52
Query 'PV query: Please provide Grade/Severity for the event.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:03:05
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:02:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 16:02:35
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:02:35
User opened query 'PV query: Please provide Grade/Severity for the event.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:02:25
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:05:13
User entered empty.	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 04:55:39
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Pending medical records' (Site from System).	Tiffany Nemecek (b) (4) (b) (4)	09 Nov 2020 23:12:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 14:21:12
User entered '1'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '12 Aug 2020'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:50:45
Query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' answered with 'subject withdrew consent. Unable to obtain any records' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:55:11
User opened query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:01:44
User closed query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:09
Query 'PV query: Please provide the discharge date, when available.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4) (b) (4)	09 Nov 2020 23:12:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:00:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 14:21:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 14:21:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Sep 2020 17:05:13
User entered ' Aug 2020' (non-conformant).	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'No (N)'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:23:15
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:07:00
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:03:13
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:02:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 16:02:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:02:35
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 17:01:27
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:05:13
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:02:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 16:02:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:02:35
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:05:13
User entered empty.	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per sponsor review, as subject did not receive second dose IP, please review Action Taken and consider updating to IP Withdrawn. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 06:49:27
Query 'Per sponsor review, as subject did not receive second dose IP, please review Action Taken and consider updating to IP Withdrawn. ' answered with 'done' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 17:15:15
DataPoint Un-verified.	Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 17:15:09
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 17:15:09
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:24:15
User opened query 'Per sponsor review, as subject did not receive second dose IP, please review Action Taken and consider updating to IP Withdrawn. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 14:16:06
User closed query 'PV Query: Please confirm the action taken. "Not applicable" as the subject had not completed both doses of study drug at the time of the event or update if appropriate.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 22:12:32
Query 'PV Query: Please confirm the action taken. "Not applicable" as the subject had not completed both doses of study drug at the time of the event or update if appropriate.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 17:24:13
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:24:06
User opened query 'PV Query: Please confirm the action taken. "Not applicable" as the subject had not completed both doses of study drug at the time of the event or update if appropriate.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 17:22:22
User closed query 'PV Query: Please confirm the action taken. "Not applicable" as the subject had not completed both doses of study drug at the time of the event or update if appropriate.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:49:04

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please confirm the action taken. "Not applicable" as the subject had not completed both doses of study drug at the time of the event or update if appropriate.' answered with 'Subject withdrew before 2nd dose.' (Site from Safety).	Brandon Essink (b) (4)	25 Nov 2020 16:56:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:56:29
User opened query 'PV Query: Please confirm the action taken. "Not applicable" as the subject had not completed both doses of study drug at the time of the event or update if appropriate.' (Site from Safety).	Brandon Essink (b) (4)	25 Nov 2020 14:35:35
User closed query 'Per CDM: Per Dosing Discontinuation form IP was withdrawn due to this SAE. Please review, reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:25:32
Query 'Per CDM: Per Dosing Discontinuation form IP was withdrawn due to this SAE. Please review, reconcile and update as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 21:37:35
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:36:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:36:54
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:24:22
User opened query 'Per CDM: Per Dosing Discontinuation form IP was withdrawn due to this SAE. Please review, reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:41:12
User closed query 'Per DM CLR-RQ: Site's response noted. However, if this AE is not the reason for dosing discontinuation, then 'Investigational Product Withdrawn' is not the appropriate response for this field. Please review/reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:02:26

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR-RQ: Site's response noted. However, if this AE is not the reason for dosing discontinuation, then 'Investigational Product Withdrawn' is not the appropriate response for this field. Please review/reconcile and update accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:34:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:34:00
User opened query 'Per DM CLR-RQ: Site's response noted. However, if this AE is not the reason for dosing discontinuation, then 'Investigational Product Withdrawn' is not the appropriate response for this field. Please review/reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:09:45
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 05:15:31
User closed query 'Per CDM: Action taken with investigational product = Dose delayed; however the Dosing discontinuation form is completed. Please update this field as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 13:17:20
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'subject withdrew consent' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 19:19:45
Query 'Per CDM: Action taken with investigational product = Dose delayed; however the Dosing discontinuation form is completed. Please update this field as appropriate. Thank you.' answered with 'subject withdrew consent' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:19:35
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Nov 2020 19:18:58
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:18:58

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Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:18:58
User opened query 'Per CDM: Action taken with investigational product = Dose delayed; however the Dosing discontinuation form is completed. Please update this field as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:04:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Dose Delayed (DOSE DELAYED)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per DM CLR - RQ: Site's response noted. However, if there is no confirmed CM taken for this AE, please update response to this field.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 05:02:45
Query 'Per DM CLR - RQ: Site's response noted. However, if there is no confirmed CM taken for this AE, please update response to this field.	Kimberly Mueller (b) (4)	04 Feb 2021 17:16:21
' answered with 'done' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Kimberly Mueller (b) (4)	04 Feb 2021 17:16:15
User entered '0' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR - RQ: Site's response noted. However, if there is no confirmed CM taken for this AE, please update response to this field.	Kimberly Mueller (b) (4)	04 Feb 2021 17:16:15
' (Site from DM).	(b) (4)	
User closed query 'Per DM CLR: RQ: Response noted, however, still no medication/s recorded for this AE. Please update and record any treatment given in its respective eCRF. Otherwise, clarify.'	(b) (4), (b) (6)	23 Jan 2021 04:28:45
(Site from DM).		
Query 'Per DM CLR: RQ: Response noted, however, still no medication/s recorded for this AE. Please update and record any treatment given in its respective eCRF. Otherwise, clarify.'	(b) (4), (b) (6)	05 Jan 2021 07:40:52
' answered with 'Subject withdrew consent. Unable to obtain any information' (Site from DM).		
User opened query 'Per DM CLR: RQ: Response noted, however, still no medication/s recorded for this AE. Please update and record any treatment given in its respective eCRF. Otherwise, clarify.'	(b) (4), (b) (6)	30 Dec 2020 17:24:45
(Site from DM).		
User opened query 'Per DM CLR: RQ: Response noted, however, still no medication/s recorded for this AE. Please update and record any treatment given in its respective eCRF. Otherwise, clarify.'	(b) (4), (b) (6)	05 Dec 2020 10:49:53
(Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Medication. However, there is no Con Med recorded that matches this AE within this timeframe. Please review and add a Con Med as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 03:30:43
Query 'Per DM CLR: Other Action Taken = Medication. However, there is no Con Med recorded that matches this AE within this timeframe. Please review and add a Con Med as appropriate or update action taken.' answered with 'pending medical records' (Site from DM).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:12:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'Per DM CLR: Other Action Taken = Medication. However, there is no Con Med recorded that matches this AE within this timeframe. Please review and add a Con Med as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:41:05
User entered 'I'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per DM CLR: Other Action Taken = Procedure. However, there is no Con Proc recorded that matches this AE within this timeframe. Please review and add a Con Proc as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 12:52:35
Query 'Per DM CLR: Other Action Taken = Procedure. However, there is no Con Proc recorded that matches this AE within this timeframe. Please review and add a Con Proc as appropriate or update action taken.' answered with 'pending medical records' (Site from DM).	Tiffany Nemecek (b) (4) (b) (4)	09 Nov 2020 23:12:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'Per DM CLR: Other Action Taken = Procedure. However, there is no Con Proc recorded that matches this AE within this timeframe. Please review and add a Con Proc as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:41:14
User entered '1'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:24:22
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:03
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' answered with 'Data updated.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:40:03
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:39:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:39:05
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:37:14
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:12
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:03
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:02:12
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' answered with 'pending medical records' (Site from Safety). DataPoint Verified.	Tiffany Nemecek (b) (4) (b) (4)	09 Nov 2020 23:12:42
	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:01:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:38:20
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:17
User closed query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:14
User closed query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:11
User closed query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:08
Query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' answered with 'Fall is not an AE' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	23 Nov 2020 23:50:05
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. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	23 Nov 2020 23:49:41
Query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	23 Nov 2020 23:49:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4)	23 Nov 2020 23:49:24
Query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4)	23 Nov 2020 23:49:14
User opened query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:35
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:22
User opened query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:11
User opened query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:01
User opened query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:37:25
User closed query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:38
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:27
User closed query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:23

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:20
Query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:33
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. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:28
Query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:15
Query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:08
User opened query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:54
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:44
User opened query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:22
User closed query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:57
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)	10 Nov 2020 18:28:46
User closed query 'PV query: Please provide laboratory/diagnostic test.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:39
User closed query 'PV query: Please provide the treatment medications. IF none, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:35
Query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:13:29
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 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:13:18
Query 'PV query: Please provide laboratory/diagnostic test.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:13:07
Query 'PV query: Please provide the treatment medications. IF none, please state so.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:12:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:32:36
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)	11 Sep 2020 14:01:48

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide laboratory/diagnostic test.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:01:31
User opened query 'PV query: Please provide the treatment medications. IF none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:01:17
User entered 'Pt. was walking her dog and tripped and broke her left hip. Patient went to Bergan Mercy ER and had surgery. Medical records are pending.'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered '1'	System	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered 'I'	System	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User entered '0'	System	03 Sep 2020 17:05:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:48:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:24:22
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:18:37

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:48:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per CDM, CLR re-query: Other Action Taken = Procedure. However, there is no Con Procedure recorded. Please review, reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM, CLR re-query: Other Action Taken = Procedure. However, there is no Con Procedure recorded. Please review, reconcile and update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:53:34
DataPoint Un-verified.	Jessica Satorie (b) (4)	24 Nov 2020 23:37:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM, CLR re-query: Other Action Taken = Procedure. However, there is no Con Procedure recorded. Please review, reconcile and update accordingly. Thank you.' (Site from DM).	Jessica Satorie (b) (4)	24 Nov 2020 23:36:59
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	Jessica Satorie (b) (4)	24 Nov 2020 23:36:59
	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 13:01:47
	(b) (4), (b) (6)	06 Nov 2020 20:24:35
	Tiffany Nemecek (b) (4)	03 Sep 2020 19:05:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '14 Aug 2020'	Jessica Satorie (b) (4)	24 Nov 2020 23:37:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Left hip fracture repair'	Jessica Satorie (b) (4)	24 Nov 2020 23:37:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'Adverse Event (AE)'	Jessica Satorie (b) (4)	24 Nov 2020 23:37:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered empty.	Jessica Satorie (b) (4)	24 Nov 2020 23:37:21

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:25:19
User entered '06 Nov 2020'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:06

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per CDM re-query: Response noted however, the reason specified for dosing discontinuation is recorded as SAE. please consider recording the primary reason for dosing discontinuation as SAE. Otherwise Clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:52:10
Query 'Per CDM re-query: Response noted however, the reason specified for dosing discontinuation is recorded as SAE. please consider recording the primary reason for dosing discontinuation as SAE. Otherwise Clarify. Thank you.' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	23 Nov 2020 23:52:48
DataPoint Un-verified.	Jessica Satorie (b) (4) (b) (4)	23 Nov 2020 23:52:41
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	23 Nov 2020 23:52:41
User opened query 'Per CDM re-query: Response noted however, the reason specified for dosing discontinuation is recorded as SAE. please consider recording the primary reason for dosing discontinuation as SAE. Otherwise Clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:13:00
User closed query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:09:15
Query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:35:47

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:18:30
	(b) (4), (b) (6)	06 Nov 2020 20:25:21
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:06

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	01 May 2021 11:48:47
User closed query 'Per CDM Re-query: Response noted , however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 07:34:10
Query 'Per CDM Re-query: Response noted , however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	26 Apr 2021 19:18:25
User entered 'AE #1' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	26 Apr 2021 19:18:10
User opened query 'Per CDM Re-query: Response noted , however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:52:45
User closed query 'Per CDM(RQ): thanks for the update : As per CCGs, Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number'. Kindly consider removing the extra text and adding just AE #. (i.e in this case AE#1)' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:52:45
Query 'Per CDM(RQ): thanks for the update : As per CCGs, Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number'. Kindly consider removing the extra text and adding just AE #. (i.e in this case AE#1)' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 19:34:42
User entered 'AE #USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:34:27
User opened query 'Per CDM(RQ): thanks for the update : As per CCGs, Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number'. Kindly consider removing the extra text and adding just AE #. (i.e in this case AE#1)' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:07:49

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:48:58

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: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:07:49
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'done' (Site from DM).	Kimberly Mueller (b) (4)	17 Mar 2021 18:11:44
Signature has been broken.	(b) (4)	
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING #USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	17 Mar 2021 18:11:39
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:42:13
Query 'Per CDM: Per sponsor review, please update specify field to AE#1. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:40:59
User opened query 'Per CDM: Per sponsor review, please update specify field to AE#1. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:05:22
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per CDM, re-query: Response noted; however, ONLY the SAE log line number should be recorded in this field and all other data removed (e.g. SAE #1). Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:50:57

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Query 'Per CDM, re-query: Response noted; however, ONLY the SAE log line number should be recorded in this field and all other data removed (e.g. SAE #1). Please review and update as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:27:41
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:27:34
User opened query 'Per CDM, re-query: Response noted; however, ONLY the SAE log line number should be recorded in this field and all other data removed (e.g. SAE #1). Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:08:04
User closed query 'Per CDM, re-query: Please note that only the SAE log line number should be recorded (e.g. SAE #1 etc). Kindly update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:44:13
Query 'Per CDM, re-query: Please note that only the SAE log line number should be recorded (e.g. SAE #1 etc). Kindly update as appropriate.' answered with 'updated' (Site from DM).	Brandon Essink (b) (4)	25 Nov 2020 16:57:39
User entered 'SAE #1-PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Brandon Essink (b) (4)	25 Nov 2020 16:57:34
User opened query 'Per CDM, re-query: Please note that only the SAE log line number should be recorded (e.g. SAE #1 etc). Kindly update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:30:49
User closed query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:51:06
Query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate.' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	24 Nov 2020 23:40:48
DataPoint Un-verified.	Jessica Satorie (b) (4)	24 Nov 2020 23:40:44

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EAB) (1725)

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Jessica Satorie (b) (4)	24 Nov 2020 23:40:44
User opened query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 10:23:40
	(b) (4), (b) (6)	06 Nov 2020 20:25:23
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. Medical records are still pending' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:42
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:34:08
User entered 'PT. broke her hip and no longer wanted to be in the study.' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:08
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:33:06
User entered empty.	Tiffany Nemecek (b) (4)	06 Nov 2020 19:33:06

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered '06 Nov 2020'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per CDM, re-query: Patient discontinued due to breaking her hip. Kindly review if the reason for discontinuation should be updated to 'SAE (Specify)'. If yes, please record SAE record number in the Other Specify field (e.g. SAE #1). Please update as appropriate or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 07:44:40
Query 'Per CDM, re-query: Patient discontinued due to breaking her hip. Kindly review if the reason for discontinuation should be updated to 'SAE (Specify)'. If yes, please record SAE record number in the Other Specify field (e.g. SAE #1). Please update as appropriate or clarify. ' answered with 'This has been updated.' (Site from DM).	Brandon Essink (b) (4) (b) (4)	25 Nov 2020 16:59:59
DataPoint Un-verified.	Brandon Essink (b) (4) (b) (4)	25 Nov 2020 16:58:50
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Brandon Essink (b) (4) (b) (4)	25 Nov 2020 16:58:50
User opened query 'Per CDM, re-query: Patient discontinued due to breaking her hip. Kindly review if the reason for discontinuation should be updated to 'SAE (Specify)'. If yes, please record SAE record number in the Other Specify field (e.g. SAE #1). Please update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:01:48
Query 'Per CDM, re-query: Reason for discontinuation is withdrawal of consent due to broken hip. Please review if the reason for discontinuation should be updated to SAE. If yes, the SAE record number should be recorded in the Other, specify field. Kindly update as appropriate or clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:00:04

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM, re-query: Reason for discontinuation is withdrawal of consent due to broken hip. Please review if the reason for discontinuation should be updated to SAE. If yes, the SAE record number should be recorded in the Other, specify field. Kindly update as appropriate or clarify. '(Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:36:01
User closed query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. '(Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:49:00
Query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:35:41
User opened query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. '(Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:18:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	01 May 2021 11:48:47
User closed query 'Per CDM re-query: Per response however the extra text is not removed yet, kindly review and consider removing the extra text and adding just AE # (i.e in this case AE#1).' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 07:33:58
Query 'Per CDM re-query: Per response however the extra text is not removed yet, kindly review and consider removing the extra text and adding just AE # (i.e in this case AE#1).' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	26 Apr 2021 19:19:40
User entered 'AE # 1' reason for change: Data Entry Error	Jessica Satorie (b) (4)	26 Apr 2021 19:19:22
User opened query 'Per CDM re-query: Per response however the extra text is not removed yet, kindly review and consider removing the extra text and adding just AE # (i.e in this case AE#1).' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:51:18
User closed query 'Per CDM(RQ): thanks for the update : As per CCGs, Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number'. Kindly consider removing the extra text and adding just AE #. (i.e in this case AE#1)' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:51:18
Query 'Per CDM(RQ): thanks for the update : As per CCGs, Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number'. Kindly consider removing the extra text and adding just AE #. (i.e in this case AE#1)' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 19:33:20
User entered 'AE #USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:33:03

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
User opened query 'Per CDM(RQ): thanks for the update : As per CCGs, Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number'. Kindly consider removing the extra text and adding just AE #. (i.e in this case AE#1)' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:06:53
User closed query 'Per CDM: Per sponsor review, if reason for study discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:06:53
Query 'Per CDM: Per sponsor review, if reason for study discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'done' (Site from DM).	Kimberly Mueller (b) (4)	17 Mar 2021 18:12:15
Signature has been broken.	Kimberly Mueller (b) (4)	17 Mar 2021 18:12:10
User entered 'PT. FRACTURED HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. #USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	17 Mar 2021 18:12:10
User opened query 'Per CDM: Per sponsor review, if reason for study discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:51:10
Query 'Per CDM: Per sponsor review, please update field to AE#1. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:50:37
User opened query 'Per CDM: Per sponsor review, please update field to AE#1. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:06:48
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User closed query 'Per CDM RQ: Please note as per the CCGs SAE Log line number is to be recorded and not the complete description. Kindly update the SAE Number only. Thanks ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:51:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
Query 'Per CDM RQ: Please note as per the CCGs SAE Log line number is to be recorded and not the complete description. Kindly update the SAE Number only. Thanks ' answered with 'done' (Site from DM). User opened query 'Per CDM RQ: Please note as per the CCGs SAE Log line number is to be recorded and not the complete description. Kindly update the SAE Number only. Thanks ' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 17:53:06
User closed query 'Per CDM RQ: Please note as per the CCGs SAE Log line number is to be recorded and not the complete description. Kindly update the SAE Number only. Thanks ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 08:25:14
User closed query 'Per CDM RQ: Per response updated, however there is no change reflecting in eCRF, kindly review and update only the SAE #1 log line number.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 08:25:14
Query 'Per CDM RQ: Per response updated, however there is no change reflecting in eCRF, kindly review and update only the SAE #1 log line number.' answered with 'The previous query asked that items were removed from narrative. No other change is needed' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 14:54:18
User opened query 'Per CDM RQ: Per response updated, however there is no change reflecting in eCRF, kindly review and update only the SAE #1 log line number.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:38:25
User closed query 'Per CDM: Please note that ONLY the SAE log line number should be recorded in this field and all other data removed (e.g. SAE #1). Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:38:25
Query 'Per CDM: Please note that ONLY the SAE log line number should be recorded in this field and all other data removed (e.g. SAE #1). Please review and update as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:33:21
User entered 'PT. FRACTURED HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:33:15
User opened query 'Per CDM: Please note that ONLY the SAE log line number should be recorded in this field and all other data removed (e.g. SAE #1). Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:08:35

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EAB) (1725)

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
User entered 'SAE #1-PT. FRACTURED HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Brandon Essink (b) (4)	25 Nov 2020 16:59:51
User entered 'PT. fractured HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P3010000001' reason for change: Data Entry Error	Brandon Essink (b) (4)	25 Nov 2020 16:58:50
User closed query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:51:26
Query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	24 Nov 2020 21:55:58
DataPoint Un-verified.	Jessica Satorie (b) (4)	24 Nov 2020 21:55:53
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P3010000001' reason for change: Data Entry Error	Jessica Satorie (b) (4)	24 Nov 2020 21:55:53
User opened query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:23:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. Medical records are still pending' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:56
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:34:02

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

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

Audit	User	Time (GMT)
User entered 'PT. broke her hip and no longer wanted to be in the study.' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:02
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:33:39
User entered empty.	Tiffany Nemecek (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:58

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:08:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

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Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	(b) (4)	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	(b) (4)	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
User entered '07/Sep/2020 13:06'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	System	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
User entered '15/Sep/2020 09:07'	System	15 Sep 2020 13:07:34

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 02:12:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 13:07:34

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	(b) (4)	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '13/Nov/2020 10:43'	(b) (4) System	13 Nov 2020 15:43:35

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 02:12:37
User entered '1' reason for change: New Information	(b) (4), (b) (6)	13 Nov 2020 15:43:35
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:58

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	System	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '21/Nov/2020 02:12'	(b) (4) System	21 Nov 2020 02:12:48

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:38:29
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 02:12:48

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	System	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '24/Nov/2020 14:38'	(b) (4) System	24 Nov 2020 14:38:40

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:49:21
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 14:38:40

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	System	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '25/Nov/2020 20:49'	(b) (4) System	25 Nov 2020 20:49:35

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 22:13:00
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 20:49:35

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	(b) (4)	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '04/Jan/2021 17:12'	(b) (4) System	04 Jan 2021 22:12:53

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 22:13:00
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 22:12:53

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered	System	07 Sep 2020 17:05:11
'USA-US005-2020-MRNA-1273-P301000001'		

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '8'	System	05 Feb 2021 14:10:39
User entered '7'	System	04 Jan 2021 22:12:53
User entered '6'	System	25 Nov 2020 20:49:35
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:48:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered '05/Feb/2021 14:10'	(b) (4) System	05 Feb 2021 14:10:39

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:48:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 12:50:15
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 14:10:39