

US3042295 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:59:16

All time stamps listed in this document are displayed in GMT

US3042295

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:59:31

Generated On: 09 Jun 2021 14:59:16

[Participant ID](#)

US3042295

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

US3042295

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3042295

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3042295

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

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

US3042295

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3042295

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Were any significant conditions reported?

Yes ☒

No ☐

US3042295

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3042295

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042295

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042295

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3042295

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:08 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 17:08
Height (<i>xxx.x</i>)	152.4 cm
Weight (<i>xxx.x</i>)	65.7 kg
BMI (<i>xxx.x</i>)	28.28756 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042295

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3042295

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Date of assessment (dd MMM yyyy) 21 AUG 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) UN UNK 1999

Date of surgery unknown False

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

Date of last menstruation unknown False

US3042295

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3042295

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

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)	True
Other	False
Specify	

US3042295

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

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

What was the participant's randomization number? 107287

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Height	ND - Not Done
Weight	ND - Not Done

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	17:08 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 17:08
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	17:37 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 17:37
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3042295

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 17:58 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 17:58

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

US3042295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

17:40 (24 HR)

Collection date and time (derived)

21 AUG 2020 17:40

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:18	21 AUG 2020 17:18
Nasopharyngeal Swab 2	No		

US3042295

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:59:33

Generated On: 09 Jun 2021 14:59:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 18:38

PC Open Date & Time

21 AUG 2020 18:18

PC Close Date & Time

21 AUG 2020 20:48

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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 97.6 °F

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

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

PC Time Stamp	21 AUG 2020 21:44
PC Open Date & Time	21 AUG 2020 21:43
PC Close Date & Time	22 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

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

22 AUG 2020 18:15

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

23 AUG 2020 12:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 12:09

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

25 AUG 2020 14:38

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 14:51

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

27 AUG 2020 13:37

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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

21 AUG 2020 18:39

PC Open Date & Time

21 AUG 2020 18:18

PC Close Date & Time

21 AUG 2020 20:48

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 21:44

PC Open Date & Time

21 AUG 2020 21:43

PC Close Date & Time

22 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 18:16

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 12:09

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 14:38

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

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

26 AUG 2020 14:51

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 13:37

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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 ☐

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 18:40
PC Open Date & Time	21 AUG 2020 18:18
PC Close Date & Time	21 AUG 2020 20:48

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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 ☐

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 21:44
PC Open Date & Time	21 AUG 2020 21:43
PC Close Date & Time	22 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

46 of 742

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

Yes ☐	
PC Time stamp	22 AUG 2020 18:16
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 742

EAB) (1725)

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

Yes ☐	
PC Time stamp	23 AUG 2020 12:07
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 742

EAB) (1725)

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

Yes ☐	
PC Time stamp	24 AUG 2020 12:10
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

52 of 742

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

		Yes ☐
PC Time stamp	25 AUG 2020 14:39	
PC Open Date & Time	25 AUG 2020 12:00	
PC Close Date & Time	26 AUG 2020 11:59	

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

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 ☐

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

		Yes ☐
PC Time stamp	26 AUG 2020 14:52	
PC Open Date & Time	26 AUG 2020 12:00	
PC Close Date & Time	27 AUG 2020 11:59	

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 742

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

		Yes ☐
PC Time stamp	27 AUG 2020 13:37	
PC Open Date & Time	27 AUG 2020 12:00	
PC Close Date & Time	28 AUG 2020 11:59	

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 28 AUG 2020 12:21

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 29 AUG 2020 20:46

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 28 AUG 2020 12:21

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3042295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	28 AUG 2020 12:21
---------------	-------------------

PC Open Date & Time	28 AUG 2020 12:00
---------------------	-------------------

PC Close Date & Time	29 AUG 2020 11:59
----------------------	-------------------

US3042295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐ Yes ☒
PC Time stamp	28 AUG 2020 12:21
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3042295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042295

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042295

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

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 _____

US3042295

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3042295

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:59:16

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

US3042295

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:16

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3042295

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:59:16

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3042295

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

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 _____

US3042295

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:16

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

US3042295

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:16

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3042295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:16

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

US3042295

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:59:31

Generated On: 09 Jun 2021 14:59:16

AEID	
Adverse event	VERTIGO
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

77 of 742

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:59:31

Generated On: 09 Jun 2021 14:59:16

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

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:59:31

Generated On: 09 Jun 2021 14:59:16

AEID

Adverse event

BLADDER INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

79 of 742

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:59:31

Generated On: 09 Jun 2021 14:59:16

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

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:59:31

Generated On: 09 Jun 2021 14:59:16

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

81 of 742

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:59:31

Generated On: 09 Jun 2021 14:59:16

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

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

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

Yes ☒

No ☐

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

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration .075

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

84 of 742

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

86 of 742

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Name of Medication CLARITIN (LORATADINE)

Prophylaxis Yes ☐
No ☒

Indication VERTIGO

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

88 of 742

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication VERTIGO

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

90 of 742

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3042295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3042295

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

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

Primary reason for dosing discontinuation

AE (specify)	☒
SAE (specify)	☐
Death	☐
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Due to SARS-COV-2	☐
Other	☐

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

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 21:59:32

Generated On: 09 Jun 2021 14:59:16

Date of study discontinuation/completion (dd MMM yyyy) 21 SEP 2020

Reason for discontinuation

AE (specify) ☒

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3042295 (Prod: Meridian Clinical Research)

US3042295

Form: Participant Creation

Generated On: 09 Jun 2021 14:59:16

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
User entered 'US3042295'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 22:44:11

US3042295

Form: Participant Creation

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:12:09

US3042295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:46
	(b) (4)	

US3042295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '21 AUG 2020'	RWS_ENDPOINT	21 Aug 2020 22:44:12
	ENDPOINT (b) (4)	
	(b) (4)	

US3042295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:42:46

US3042295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'SCRN'	(b) (4), (b) (6) System	24 Aug 2020 15:42:46

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 22:44:13

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '61'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'YEARS'	(b) (4), (b) (6) System	24 Aug 2020 15:42:53

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '61'	(b) (4), (b) (6) System	21 Aug 2020 23:07:58

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Female (F)'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '1'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:42:53
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '21 Aug 2020'	Rylea Gulick (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'Aug 2020'	(b) (4), (b) (6) System	21 Aug 2020 23:07:58

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '2020'	(b) (4), (b) (6) System	21 Aug 2020 23:07:58

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Amendment 2 (2)'	Rylea Gulick (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	RWS_ENDPOINT	21 Aug 2020 22:44:12
	ENDPOINT (b) (4)	
	(b) (4)	

US3042295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 23:08:00

US3042295

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 23:08:00

US3042295

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:59:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:43:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:43:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:43:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:43:00
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:00
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	14 Sep 2020 05:27:31
' (Site from DM).		
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 16:32:06
' answered with 'WILL ADD CONDITION ASSOCIATED' (Site from DM).		
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	10 Sep 2020 08:57:24
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:47:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:47:40
Data point term sent to Coder	System	24 Aug 2020 15:46:05
User entered 'COMPLETE HYSTERECTOMY'	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'UN UNK 1999'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:45:52
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'UN UNK 1999'	Rylea Gulick (b) (4)	24 Aug 2020 15:45:52
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'Jan 1999'	(b) (4), (b) (6) System	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '1999'	(b) (4), (b) (6) System	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'Jan 1999'	(b) (4), (b) (6) System	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '1999'	(b) (4), (b) (6) System	24 Aug 2020 15:45:52

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:47:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:47:40
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 15:46:08
User entered 'HYPOTHYROIDISM'	Rylea Gulick (b) (4)	24 Aug 2020 15:46:08
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'UN UNK 2000'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:46:08

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:46:08

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:46:08

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:46:08
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:46:08
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'Jan 2000'	(b) (4), (b) (6) System	24 Aug 2020 15:46:08

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '2000'	(b) (4), (b) (6) System	24 Aug 2020 15:46:08

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:46:08

US3042295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:46:08

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:48:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:48:35
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 15:47:09
User entered 'HYPERCHOLESTEROLEMIA'	Rylea Gulick (b) (4)	24 Aug 2020 15:46:18
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'UN UNK 2019'	Rylea Gulick (b) (4)	24 Aug 2020 15:46:18
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:46:18
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:46:18

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:46:18

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:46:18

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'Jan 2019'	(b) (4), (b) (6) System	24 Aug 2020 15:46:18

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '2019'	(b) (4), (b) (6) System	24 Aug 2020 15:46:18

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:46:18

US3042295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:46:18

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:34:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:34:45
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 16:33:54
User entered 'MENORRHAGIA'	Rylea Gulick (b) (4)	10 Sep 2020 16:33:47
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'UN UNK 1990' reason for change:	Rylea Gulick (b) (4)	10 Sep 2020 20:00:35
Data Entry Error	(b) (4)	
User entered 'UN UNK 1998'	Rylea Gulick (b) (4)	10 Sep 2020 16:33:47
	(b) (4)	

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'UN UNK 1999'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'Jan 1990'	(b) (4), (b) (6)	
	System	10 Sep 2020 20:00:35
User entered 'Jan 1998'	System	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '1990'	(b) (4), (b) (6)	
	System	10 Sep 2020 20:00:35
User entered '1998'	System	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'Jan 1999'	(b) (4), (b) (6) System	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '1999'	(b) (4), (b) (6) System	10 Sep 2020 16:33:47

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:47:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:47:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:43:36
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '21 Aug 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '17:08' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered '21 Aug 2020 17:08'	(b) (4), (b) (6)	
	System	24 Aug 2020 15:47:00
User entered empty.	System	24 Aug 2020 15:43:36

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '152.4' cm reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 23:08:00

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '65.7' kg reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 23:08:00

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
Amendment Manager: User entered '28.28756'	(b) (4), (b) (6)	
User entered '28.3'	System	17 Sep 2020 00:19:38
User entered empty.	System	24 Aug 2020 15:47:00
DataPoint set to visible.	System	24 Aug 2020 15:43:36
	System	21 Aug 2020 23:08:00

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	24 Aug 2020 15:47:00
User entered empty.	System	24 Aug 2020 15:43:36
DataPoint set to visible.	System	21 Aug 2020 23:08:00

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 07:41:24
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:50:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:50:03
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:57:03
User entered '36.9' C reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:00
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:43:36

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:50:03
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:50:03
change Data Entry Error	(b) (4)	
User entered '69' reason for change: Data Entry	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'bpm'	(b) (4), (b) (6)	
	System	24 Aug 2020 15:47:00
User entered empty.	System	24 Aug 2020 15:43:36

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:50:03
	(b) (4)	
User entered '14' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'breaths/min'	(b) (4), (b) (6)	
	System	24 Aug 2020 15:47:00
User entered empty.	System	24 Aug 2020 15:43:36

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:50:03
	(b) (4)	
User entered '147' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'mmHg'	(b) (4), (b) (6)	
	System	24 Aug 2020 15:47:00
User entered empty.	System	24 Aug 2020 15:43:36

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:50:03
	(b) (4)	
User entered '75' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:47:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:43:36
	(b) (4)	

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User entered 'mmHg'	(b) (4), (b) (6)	
	System	24 Aug 2020 15:47:00
User entered empty.	System	24 Aug 2020 15:43:36

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:15:53

US3042295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:15:53

US3042295

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:05

US3042295

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:05

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '21 Aug 2020'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:13
	(b) (4)	

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:13
	(b) (4)	

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 15:47:13

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:47:13
	(b) (4)	

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'UN UNK 1999'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:13

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:13
	(b) (4)	

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:47:13
	(b) (4)	

US3042295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:16

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:13
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

[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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

[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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

[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)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '1'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:36

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:47:36
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:43

US3042295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:43

US3042295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:43

US3042295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'VISIT1'	(b) (4), (b) (6) System	24 Aug 2020 15:47:43

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 22:44:21

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '107287'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 22:44:21

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 22:44:21
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:51

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:47:51
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:51

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 15:47:51
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:47:51

US3042295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:16

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 09:10:28
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 17:55:33
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 17:55:30
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:15:42
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:00
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:15:41

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:46:55
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	29 Oct 2020 13:48:13
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	29 Oct 2020 13:48:10
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:12:41
User entered '152.4' cm	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	29 Oct 2020 13:48:10
change Data Entry Error	(b) (4)	
User entered '65.7' kg	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:46:55
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	29 Oct 2020 13:48:13
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	29 Oct 2020 13:48:10
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:12:41
User entered '152.4' cm	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	29 Oct 2020 13:48:10
change Data Entry Error	(b) (4)	
User entered '65.7' kg	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '17:08'	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered '21 Aug 2020 17:08'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '69'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '147'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '75'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:46:55
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	29 Oct 2020 13:48:13
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	29 Oct 2020 13:48:10
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:12:41
User entered '152.4' cm	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	29 Oct 2020 13:48:10
change Data Entry Error	(b) (4)	
User entered '65.7' kg	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	24 Aug 2020 15:48:57
User entered '17:37' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:48:57
	(b) (4)	
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	24 Aug 2020 15:48:28
User entered '16:37'	Rylea Gulick (b) (4)	24 Aug 2020 15:48:28
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered '21 Aug 2020 17:37'	(b) (4), (b) (6)	
	System	24 Aug 2020 15:48:57
User entered '21 Aug 2020 16:37'	System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '36.8' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '76'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '16'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '148'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '90'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 15:48:28

US3042295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 15:49:29
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:49:29

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 23:08:12

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 23:08:12
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 23:08:12
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 23:08:12

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '17:58'	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 23:08:12
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered '21 Aug 2020 17:58'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 23:08:12
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'ONCE'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 15:49:35
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 15:49:43
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		24 Aug 2020 15:49:43
User entered '21 Aug 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 15:49:43
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 15:49:35
User entered '22 Aug 2020'	Rylea Gulick (b) (4)	24 Aug 2020 15:49:35
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 17:27:12
User entered '17:40' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 17:27:12
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 15:49:35
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 15:49:35
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered '21 Aug 2020 17:40'	(b) (4), (b) (6)	
	System	09 Sep 2020 17:27:12
User entered empty.	System	24 Aug 2020 15:49:35

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:59:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 15:49:52
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '17:18'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered '21 Aug 2020 17:18'	(b) (4), (b) (6) System	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:49:52

US3042295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 15:49:57
	(b) (4)	

US3042295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:32
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 15:49:57

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:38:44', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '5285cd6a-ac0b-4e3f-9913-b4241b7d7174' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 23:39:01
	System	21 Aug 2020 23:39:01

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:38:50', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '5285cd6a-ac0b-4e3f-9913-b4241b7d7174' User entered '98.2'	(b) (4), (b) (6) System	21 Aug 2020 23:39:01
	System	21 Aug 2020 23:39:01

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:38:55', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '5285cd6a-ac0b-4e3f-9913-b4241b7d7174'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 23:39:01

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:38:59', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '5285cd6a-ac0b-4e3f-9913-b4241b7d7174' User entered '21 Aug 2020 18:38'	(b) (4), (b) (6) System	21 Aug 2020 23:39:01
	System	21 Aug 2020 23:39:01

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 18:18'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 20:48'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:43:46', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '4653eda7-cb2c-475f-87d4-530775db8187' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:04
	System	22 Aug 2020 02:44:04

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:43:53', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '4653eda7-cb2c-475f-87d4-530775db8187' User entered '97.6'	(b) (4), (b) (6) System	22 Aug 2020 02:44:04
	System	22 Aug 2020 02:44:04

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:43:57', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '4653eda7-cb2c-475f-87d4-530775db8187' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:04
	System	22 Aug 2020 02:44:04

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:01', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '4653eda7-cb2c-475f-87d4-530775db8187' User entered '21 Aug 2020 21:44'	(b) (4), (b) (6) System	22 Aug 2020 02:44:04
	System	22 Aug 2020 02:44:04

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 21:43'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 2'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:15:25', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2af756d9-6be1-421b-bbda-8ee847d05d5e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 23:15:49
	System	22 Aug 2020 23:15:49

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:15:32', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2af756d9-6be1-421b-bbda-8ee847d05d5e' User entered '97.3'	(b) (4), (b) (6) System	22 Aug 2020 23:15:49
	System	22 Aug 2020 23:15:49

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:15:35', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2af756d9-6be1-421b-bbda-8ee847d05d5e' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:15:49
	System	22 Aug 2020 23:15:49

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:15:44', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2af756d9-6be1-421b-bbda-8ee847d05d5e' User entered '22 Aug 2020 18:15'	(b) (4), (b) (6) System	22 Aug 2020 23:15:49
	System	22 Aug 2020 23:15:49

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 3'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:03', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7f5cf898-111c-4be0-ad6c-cfe8d93d76f2'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:06:19
User entered 'Yes (Y)'	System	23 Aug 2020 17:06:19

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:08', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7f5cf898-111c-4be0-ad6c-cfe8d93d76f2' User entered '97.3'	(b) (4), (b) (6) System	23 Aug 2020 17:06:19
	System	23 Aug 2020 17:06:19

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:11', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7f5cf898-111c-4be0-ad6c-cfe8d93d76f2'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:06:19
User entered 'No (N)'	System	23 Aug 2020 17:06:19

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:16', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7f5cf898-111c-4be0-ad6c-cfe8d93d76f2'	(b) (4), (b) (6) System	23 Aug 2020 17:06:19
User entered '23 Aug 2020 12:06'	System	23 Aug 2020 17:06:19

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 4'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:08:50', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '16c05baa-40f7-4fa1-9f77-99d7cd6b53a9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 17:09:07
	System	24 Aug 2020 17:09:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:08:57', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '16c05baa-40f7-4fa1-9f77-99d7cd6b53a9' User entered '98.1'	(b) (4), (b) (6) System	24 Aug 2020 17:09:07
	System	24 Aug 2020 17:09:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:08:59', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '16c05baa-40f7-4fa1-9f77-99d7cd6b53a9' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 17:09:07
	System	24 Aug 2020 17:09:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:04', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '16c05baa-40f7-4fa1-9f77-99d7cd6b53a9' User entered '24 Aug 2020 12:09'	(b) (4), (b) (6) System	24 Aug 2020 17:09:07
	System	24 Aug 2020 17:09:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 5'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:11', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a30aa3d2-8e65-4ce7-8d74-a5a2ef8efb8e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Aug 2020 19:38:27
	System	25 Aug 2020 19:38:27

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:18', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a30aa3d2-8e65-4ce7-8d74-a5a2ef8efb8e' User entered '98.4'	(b) (4), (b) (6) System	25 Aug 2020 19:38:27
	System	25 Aug 2020 19:38:27

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:22', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a30aa3d2-8e65-4ce7-8d74-a5a2ef8efb8e' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 19:38:27
	System	25 Aug 2020 19:38:27

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:25', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a30aa3d2-8e65-4ce7-8d74-a5a2ef8efb8e' User entered '25 Aug 2020 14:38'	(b) (4), (b) (6) System	25 Aug 2020 19:38:27
	System	25 Aug 2020 19:38:27

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 6'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:20', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '72724417-1029-4321-8ccd-82c8266bd627'	(b) (4), (b) (6)	
	System	26 Aug 2020 19:51:34
User entered 'Yes (Y)'	System	26 Aug 2020 19:51:34

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:26', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '72724417-1029-4321-8ccd-82c8266bd627'	(b) (4), (b) (6)	
User entered '98.2'	System	26 Aug 2020 19:51:34

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:29', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '72724417-1029-4321-8ccd-82c8266bd627'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 19:51:34

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:32', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '72724417-1029-4321-8ccd-82c8266bd627'	(b) (4), (b) (6)	
	System	26 Aug 2020 19:51:34
User entered '26 Aug 2020 14:51'	System	26 Aug 2020 19:51:34

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 7'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:36:55', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '360bb6f8-9416-41d0-af4f-6c1d4df029f7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:07
	System	27 Aug 2020 18:37:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:00', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '360bb6f8-9416-41d0-af4f-6c1d4df029f7' User entered '98.8'	(b) (4), (b) (6) System	27 Aug 2020 18:37:07
	System	27 Aug 2020 18:37:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:03', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '360bb6f8-9416-41d0-af4f-6c1d4df029f7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 18:37:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:05', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '360bb6f8-9416-41d0-af4f-6c1d4df029f7' User entered '27 Aug 2020 13:37'	(b) (4), (b) (6) System	27 Aug 2020 18:37:07
	System	27 Aug 2020 18:37:07

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:39:33', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2a02a8e3-73fd-44d2-8718-e5f53e6f41cb' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 23:39:59
	System	21 Aug 2020 23:39:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:39:36', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2a02a8e3-73fd-44d2-8718-e5f53e6f41cb' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 23:39:59
	System	21 Aug 2020 23:39:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:39:39', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2a02a8e3-73fd-44d2-8718-e5f53e6f41cb' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 23:39:59
	System	21 Aug 2020 23:39:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:39:55', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2a02a8e3-73fd-44d2-8718-e5f53e6f41cb' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 23:39:59
	System	21 Aug 2020 23:39:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:39:57', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2a02a8e3-73fd-44d2-8718-e5f53e6f41cb' User entered '21 Aug 2020 18:39'	(b) (4), (b) (6) System	21 Aug 2020 23:39:59
	System	21 Aug 2020 23:39:59

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 18:18'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 20:48'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:07', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'f87c352e-6f4e-4040-bc7b-c246d2a38307' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:37
	System	22 Aug 2020 02:44:37

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:15', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'f87c352e-6f4e-4040-bc7b-c246d2a38307' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:37
	System	22 Aug 2020 02:44:37

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:18', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'f87c352e-6f4e-4040-bc7b-c246d2a38307' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:37
	System	22 Aug 2020 02:44:37

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:20', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'f87c352e-6f4e-4040-bc7b-c246d2a38307' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:37
	System	22 Aug 2020 02:44:37

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:24', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'f87c352e-6f4e-4040-bc7b-c246d2a38307' User entered '21 Aug 2020 21:44'	(b) (4), (b) (6) System	22 Aug 2020 02:44:37
	System	22 Aug 2020 02:44:37

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 21:43'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 2'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:25', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '15c239b4-fad7-44bc-ab61-4b7785f3ebe2' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:42
	System	22 Aug 2020 23:16:42

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:29', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '15c239b4-fad7-44bc-ab61-4b7785f3ebe2' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:42
	System	22 Aug 2020 23:16:42

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:34', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '15c239b4-fad7-44bc-ab61-4b7785f3ebe2' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:42
	System	22 Aug 2020 23:16:42

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:37', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '15c239b4-fad7-44bc-ab61-4b7785f3ebe2' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:42
	System	22 Aug 2020 23:16:42

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:39', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '15c239b4-fad7-44bc-ab61-4b7785f3ebe2' User entered '22 Aug 2020 18:16'	(b) (4), (b) (6) System	22 Aug 2020 23:16:42
	System	22 Aug 2020 23:16:42

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 3'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:26', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a5652368-267d-4274-9eed-5e23a7d43bf1' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 17:06:43
	System	23 Aug 2020 17:06:43

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:29', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a5652368-267d-4274-9eed-5e23a7d43bf1' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 17:06:43
	System	23 Aug 2020 17:06:43

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:32', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a5652368-267d-4274-9eed-5e23a7d43bf1' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 17:06:43
	System	23 Aug 2020 17:06:43

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:38', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a5652368-267d-4274-9eed-5e23a7d43bf1' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 17:06:43
	System	23 Aug 2020 17:06:43

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:06:40', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a5652368-267d-4274-9eed-5e23a7d43bf1' User entered '23 Aug 2020 12:06'	(b) (4), (b) (6) System	23 Aug 2020 17:06:43
	System	23 Aug 2020 17:06:43

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 4'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:07', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ad211d3b-9daf-4767-8611-61fea684b3b2' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 17:09:21
	System	24 Aug 2020 17:09:21

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:10', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ad211d3b-9daf-4767-8611-61fea684b3b2' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 17:09:21
	System	24 Aug 2020 17:09:21

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:12', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ad211d3b-9daf-4767-8611-61fea684b3b2' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 17:09:21
	System	24 Aug 2020 17:09:21

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:16', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ad211d3b-9daf-4767-8611-61fea684b3b2' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 17:09:21
	System	24 Aug 2020 17:09:21

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:19', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ad211d3b-9daf-4767-8611-61fea684b3b2' User entered '24 Aug 2020 12:09'	(b) (4), (b) (6) System	24 Aug 2020 17:09:21
	System	24 Aug 2020 17:09:21

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 5'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:29', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7affd6d0-7f5c-41fb-b59f-5063ecf89ac2'	(b) (4), (b) (6)	
	System	25 Aug 2020 19:38:40
User entered 'None (1)'	System	25 Aug 2020 19:38:40

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:31', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7affd6d0-7f5c-41fb-b59f-5063ecf89ac2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 19:38:40

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:33', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7affd6d0-7f5c-41fb-b59f-5063ecf89ac2'	(b) (4), (b) (6)	
	System	25 Aug 2020 19:38:40
User entered 'No (N)'	System	25 Aug 2020 19:38:40

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:36', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7affd6d0-7f5c-41fb-b59f-5063ecf89ac2'	(b) (4), (b) (6)	
	System	25 Aug 2020 19:38:40
User entered 'None (1)'	System	25 Aug 2020 19:38:40

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:38', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '7affd6d0-7f5c-41fb-b59f-5063ecf89ac2'	(b) (4), (b) (6) System	25 Aug 2020 19:38:40
User entered '25 Aug 2020 14:38'	System	25 Aug 2020 19:38:40

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 6'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:37', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '1265ae8e-6b3d-40f3-8ee6-378aee58919b' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 19:51:49
	System	26 Aug 2020 19:51:49

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:39', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '1265ae8e-6b3d-40f3-8ee6-378aee58919b' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 19:51:49
	System	26 Aug 2020 19:51:49

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:42', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '1265ae8e-6b3d-40f3-8ee6-378aee58919b' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 19:51:49
	System	26 Aug 2020 19:51:49

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:44', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '1265ae8e-6b3d-40f3-8ee6-378aee58919b' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 19:51:49
	System	26 Aug 2020 19:51:49

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:47', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '1265ae8e-6b3d-40f3-8ee6-378aee58919b' User entered '26 Aug 2020 14:51'	(b) (4), (b) (6) System	26 Aug 2020 19:51:49
	System	26 Aug 2020 19:51:49

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 7'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:10', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ef1b18d0-a704-4f87-abae-719a605d5fc5' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:23
	System	27 Aug 2020 18:37:23

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:13', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ef1b18d0-a704-4f87-abae-719a605d5fc5' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:23
	System	27 Aug 2020 18:37:23

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:14', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ef1b18d0-a704-4f87-abae-719a605d5fc5' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:23
	System	27 Aug 2020 18:37:23

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:17', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ef1b18d0-a704-4f87-abae-719a605d5fc5'	(b) (4), (b) (6)	27 Aug 2020 18:37:23
User entered 'None (1)'	System	27 Aug 2020 18:37:23

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:20', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ef1b18d0-a704-4f87-abae-719a605d5fc5' User entered '27 Aug 2020 13:37'	(b) (4), (b) (6) System	27 Aug 2020 18:37:23
	System	27 Aug 2020 18:37:23

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:14', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:21', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:26', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:29', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:33', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:35', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:39', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T18:40:42', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '148661e4-6b1c-47b3-8959-6a45e4b9e2d8' User entered '21 Aug 2020 18:40'	(b) (4), (b) (6) System	21 Aug 2020 23:40:43
	System	21 Aug 2020 23:40:43

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 18:18'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 20:48'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:30', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:33', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:35', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:41', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:46', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:48', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:54', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-21T21:44:56', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '85471140-6e56-4acf-9806-f0ceca55742d' User entered '21 Aug 2020 21:44'	(b) (4), (b) (6) System	22 Aug 2020 02:44:59
	System	22 Aug 2020 02:44:59

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '21 Aug 2020 21:43'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 2'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:15:50', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:15:56', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:15:59', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:04', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:08', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:10', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:17', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-22T18:16:20', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '17e2e5ac-b5b9-4182-b93d-0850597d8fc2' User entered '22 Aug 2020 18:16'	(b) (4), (b) (6) System	22 Aug 2020 23:16:27
	System	22 Aug 2020 23:16:27

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 3'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:00', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:07:45
	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:06', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:07:45
	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:09', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:07:45
	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:13', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:07:45
	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:20', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102'	(b) (4), (b) (6)	
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:25', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:07:45
User entered 'Some interference with activity not requiring medical attention (2)'	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:32', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 17:07:45
	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-23T12:07:43', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '290f32e2-0f66-4258-a095-22c5cb202102' User entered '23 Aug 2020 12:07'	(b) (4), (b) (6) System	23 Aug 2020 17:07:45
	System	23 Aug 2020 17:07:45

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 4'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:38', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2'	(b) (4), (b) (6)	
User entered 'No interference with activity (1)'	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:41', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:10:07
	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:46', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:10:07
	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:49', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:10:07
	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:52', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:10:07
	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:09:56', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:10:07
	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:10:02', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 17:10:07
	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-24T12:10:05', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '217abac1-9203-42e2-909e-ac9c6568c0d2' User entered '24 Aug 2020 12:10'	(b) (4), (b) (6) System	24 Aug 2020 17:10:07
	System	24 Aug 2020 17:10:07

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 5'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:54', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7'	(b) (4), (b) (6)	
	System	25 Aug 2020 19:39:19
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:38:58', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 19:39:19
	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:39:00', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 19:39:19
	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:39:03', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 19:39:19
	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:39:05', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 19:39:19
	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:39:09', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7'	(b) (4), (b) (6)	
	System	25 Aug 2020 19:39:19
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:39:15', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Aug 2020 19:39:19
	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-25T14:39:17', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c783dacb-fc48-42db-a8fc-7b2f16a18db7' User entered '25 Aug 2020 14:39'	(b) (4), (b) (6) System	25 Aug 2020 19:39:19
	System	25 Aug 2020 19:39:19

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 6'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:55', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:51:58', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:52:00', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:52:05', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:52:07', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:52:09', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:52:24', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-26T14:52:26', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ae151e9f-a122-4fba-9ada-874a17fe78db' User entered '26 Aug 2020 14:52'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28
	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 23:08:12
User entered 'Day 7'	System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:27', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c'	(b) (4), (b) (6)	
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:35', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56
	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:38', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56
	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:44', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56
	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:47', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56
	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:49', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56
	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:52', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56
	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-27T13:37:54', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '682d4ac1-4981-4ee8-b934-334b7586216c' User entered '27 Aug 2020 13:37'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56
	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 23:08:12

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	26 Aug 2020 19:52:28
User entered 'Day 8'	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:59:16

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:17', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c3b5c86b-3111-45e0-9773-8fd855cbd34c' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	28 Aug 2020 17:21:24
	System	28 Aug 2020 17:21:24

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:20', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'c3b5c86b-3111-45e0-9773-8fd855cbd34c' User entered '28 Aug 2020 12:21'	(b) (4), (b) (6) System	28 Aug 2020 17:21:24
	System	28 Aug 2020 17:21:24

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 18:37:56
User entered 'Day 9'	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:59:16

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-29T20:45:58', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a7a9181b-c803-4b39-af8f-a9d0b1cd6c5f' User entered 'None (0)'	(b) (4), (b) (6) System	30 Aug 2020 01:46:05
	System	30 Aug 2020 01:46:05

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-29T20:46:00', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'a7a9181b-c803-4b39-af8f-a9d0b1cd6c5f' User entered '29 Aug 2020 20:46'	(b) (4), (b) (6) System	30 Aug 2020 01:46:05
	System	30 Aug 2020 01:46:05

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 18:37:56
User entered 'Day 8'	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:59:16

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:24', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ce44d3a4-258d-482c-bc8a-75fbb45f1b53' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 17:21:27
	System	28 Aug 2020 17:21:27

US3042295

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:26', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: 'ce44d3a4-258d-482c-bc8a-75fbb45f1b53' User entered '28 Aug 2020 12:21'	(b) (4), (b) (6) System	28 Aug 2020 17:21:27
	System	28 Aug 2020 17:21:27

US3042295

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 18:37:56
User entered 'Day 8'	System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:59:16

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:29', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2ea6daba-4937-41d0-a717-c257d94eacd9' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 17:21:33
	System	28 Aug 2020 17:21:33

US3042295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:31', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '2ea6daba-4937-41d0-a717-c257d94eacd9' User entered '28 Aug 2020 12:21'	(b) (4), (b) (6) System	28 Aug 2020 17:21:33
	System	28 Aug 2020 17:21:33

US3042295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 18:37:56

US3042295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	26 Aug 2020 19:52:28
User entered 'Day 8'	System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:37', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '01e82c48-cea5-46ea-a092-b052d1b3e7a3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Aug 2020 17:21:42
	System	28 Aug 2020 17:21:42

US3042295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC1D9B19-FF16-43C0-A482-44593149725B)', Time: '2020-08-28T12:21:39', User OID: 'PatientReportedOutcome (US3042295)', ODM File OID: '01e82c48-cea5-46ea-a092-b052d1b3e7a3' User entered '28 Aug 2020 12:21'	(b) (4), (b) (6) System	28 Aug 2020 17:21:42
	System	28 Aug 2020 17:21:42

US3042295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28

US3042295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:56
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	26 Aug 2020 19:52:28

US3042295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:33
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:47:48

US3042295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:33
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 06:17:48
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Site aware patient outside of window' (Site from System).	Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:48:48
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Sep 2020 22:47:48
User entered '1 Sep 2020'	Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:47:48

US3042295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:33
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:47:48

US3042295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:33
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:47:48

US3042295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:33
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:49:01

US3042295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:33
User entered '1'	(b) (4), (b) (6) System	05 Sep 2020 22:49:01

US3042295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:49:11

US3042295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '5 Sep 2020'	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:49:11

US3042295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:49:11

US3042295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	05 Sep 2020 22:49:11

US3042295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	05 Sep 2020 22:49:18
	(b) (4)	

US3042295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:29
User entered '1'	(b) (4), (b) (6) System	05 Sep 2020 22:49:18

US3042295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	23 Sep 2020 19:02:42
	(b) (4)	

US3042295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:02:42
	(b) (4)	

US3042295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:02:42
	(b) (4)	

US3042295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 21:59:34
User entered empty.	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:02:42

US3042295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	23 Sep 2020 19:02:46
	(b) (4)	

US3042295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered empty.	(b) (4), (b) (6) System	23 Sep 2020 19:02:46

US3042295

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:59:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Per the eduary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Headache to the AE page or else clarify.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 08:45:30
	(b) (4), (b) (6)	
Query 'Per CDM: Per the eduary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Headache to the AE page or else clarify.' answered with 'ENTRY ADDED' (Site from DM).	Rylea Gulick (b) (4)	14 Apr 2021 20:01:52
	(b) (4)	
User opened query 'Per CDM: Per the eduary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Headache to the AE page or else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 16:26:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	23 Sep 2020 19:05:25
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:33:00
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:12:09

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 19:07:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 19:07:46
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 19:06:45
User entered 'VERTIGO'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered empty.	(b) (4), (b) (6) System	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered empty.	(b) (4), (b) (6) System	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	30 Sep 2020 21:57:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 21:57:34
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Sep 2020 21:57:34
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:05:46
User entered empty.	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 21:57:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 21:57:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	30 Sep 2020 21:57:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:05:46
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Please note that per page 37 of CCGs v2.0, an Adverse event should be recorded as 'Not applicable' only if it has started before the first dose. In all other cases 'Related' or 'Not related' should be selected for Relationship to Study Procedure. Please update as appropriate, else clarify.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:57:58
Query 'Per CDM: Please note that per page 37 of CCGs v2.0, an Adverse event should be recorded as 'Not applicable' only if it has started before the first dose. In all other cases 'Related' or 'Not related' should be selected for Relationship to Study Procedure. Please update as appropriate, else clarify.	Rylea Gulick (b) (4)	05 Nov 2020 18:05:34
' answered with 'NOT APPLICABLE PER PI' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Please note that per page 37 of CCGs v2.0, an Adverse event should be recorded as 'Not applicable' only if it has started before the first dose. In all other cases 'Related' or 'Not related' should be selected for Relationship to Study Procedure. Please update as appropriate, else clarify.	(b) (4), (b) (6)	30 Oct 2020 06:57:03
' (Site from DM).		
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 21:57:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 21:57:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	30 Sep 2020 21:57:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Sep 2020 19:05:46
	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Per dosing discontinuation form the dosing was discontinued due to AE #1. Please review to update the Action taken with investigational product as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 07:50:52
Query 'Per CDM: Per dosing discontinuation form the dosing was discontinued due to AE #1. Please review to update the Action taken with investigational product as appropriate, else clarify. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 15:08:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 15:08:05
User opened query 'Per CDM: Per dosing discontinuation form the dosing was discontinued due to AE #1. Please review to update the Action taken with investigational product as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:49:40
User entered 'None (NONE)'	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '1'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:05:46
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '0'	(b) (4), (b) (6) System	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	23 Sep 2020 19:05:46

US3042295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:12:09

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:13:26

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Bladder infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	02 Dec 2020 20:53:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 20:53:53
Data point term sent to Coder	System	02 Dec 2020 20:52:49
User entered 'BLADDER INFECTION'	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '24 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User entered empty.	(b) (4), (b) (6) System	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '07 Sep 2020'	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User entered empty.	(b) (4), (b) (6) System	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'None (NONE)'	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '1'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	02 Dec 2020 20:52:04
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User entered '0'	(b) (4), (b) (6) System	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:26
User entered '1'	(b) (4), (b) (6) System	02 Dec 2020 20:52:04

US3042295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:13:26

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:13:34

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGt: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:03:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:03:54
	(b) (4)	
Data point term sent to Coder	System	14 Apr 2021 20:02:40
User entered 'HEADACHE'	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '24 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '29 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:52:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:52:37
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 18:52:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 20:02:31
User entered empty.	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:52:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:52:37
User entered 'Related (RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 18:52:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 20:02:31
User entered empty.	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:52:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:52:37
User entered 'Related (RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 18:52:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 20:02:31
User entered empty.	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'None (NONE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '1'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	14 Apr 2021 20:02:31
	(b) (4)	

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User entered '0'	(b) (4), (b) (6) System	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:13:34
User entered '0'	(b) (4), (b) (6) System	14 Apr 2021 20:02:31

US3042295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:13:34

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:59:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:14:31
Query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'SUBJECT DID NOT REPORT WHAT MEDICATION WAS TAKEN' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 21:38:24
User opened query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:08:23
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:25:38

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:27:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:27:35
Data point term sent to Coder	System	24 Aug 2020 16:26:59
User entered 'SYNTHROID'	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'HYPOTHYROIDISM'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '.075'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'mg (mg)'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'UN UNK 2010'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:20
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '804 (804)'	(b) (4), (b) (6) System	24 Aug 2020 16:26:20

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 16:27:35
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Aug 2020 16:27:35
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	24 Aug 2020 16:27:01
User entered 'ATORVASTATIN'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:56

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '10'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:56

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'once daily (QD)'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 16:26:56

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'UN UNK 2019'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 16:26:56
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 16:26:56

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 16:26:56

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '804 (804)'	(b) (4), (b) (6) System	24 Aug 2020 16:26:56

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:57:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:57:41
Data point term sent to Coder	System	23 Sep 2020 19:06:48
User entered 'CLARITIN (LORATADINE)'	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:30

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'VERTIGO'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '10'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:30

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'once daily (QD)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:30

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:30

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:30
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	23 Sep 2020 19:06:30

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	23 Sep 2020 19:06:30

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '804 (804)'	(b) (4), (b) (6) System	23 Sep 2020 19:06:30

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensiz (b) (4)	28 Apr 2021 21:59:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Sep 2020 19:07:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 19:07:46
Data point term sent to Coder User entered 'MUCINEX'	System Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:48 23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'VERTIGO'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '600'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'mg (mg)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered '21 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	23 Sep 2020 19:06:47
	(b) (4)	

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '1'	(b) (4), (b) (6) System	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User entered '804 (804)'	(b) (4), (b) (6) System	23 Sep 2020 19:06:47

US3042295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:59:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:12:09
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:59:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 15:32:56
	(b) (4)	

US3042295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:59:16

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '21 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:31

US3042295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:59:16

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Per End of Study form subject Withdrew consent due to being diagnosed with vertigo. Please review if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page and update the action taken to study drug withdrawn on the AE page. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 07:46:37
Query 'Per CDM: Per End of Study form subject Withdrew consent due to being diagnosed with vertigo. Please review if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page and update the action taken to study drug withdrawn on the AE page. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:50:48
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:50:44
User opened query 'Per CDM: Per End of Study form subject Withdrew consent due to being diagnosed with vertigo. Please review if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page and update the action taken to study drug withdrawn on the AE page. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:35:34
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:31

US3042295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 08:58:57
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:14:53
User entered 'AE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:14:12
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:16:59
User entered 'AE 1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:13
User entered 'AE 2' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:50:44
User entered 'SUBJECT WAS DIAGNOSED WITH VERTIGO AND WISHED TO NOT PARTICIPANT IN STUDY ANY FURTHER TO FOCUS ON THEIR HEALTH'	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:31

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:16

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered '21 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:52

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:16

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4) (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Per End of Study form subject Withdrew consent due to being diagnosed with vertigo. Please review if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page and update the action taken to study drug withdrawn on the AE page. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:46:35
Query 'Per CDM: Per End of Study form subject Withdrew consent due to being diagnosed with vertigo. Please review if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page and update the action taken to study drug withdrawn on the AE page. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:51:03
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:51:00
User opened query 'Per CDM: Per End of Study form subject Withdrew consent due to being diagnosed with vertigo. Please review if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page and update the action taken to study drug withdrawn on the AE page. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:52:10
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:52

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:16

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)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 08:59:04
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:14:03
User entered 'AE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:13:58
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:16:52
User entered 'AE 1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:52:18
User entered 'AE 2' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:51:00
User entered 'SUBJECT WAS DIAGNOSED WITH VERTIGO AND WISHED TO NOT PARTICIPANT IN STUDY ANY FURTHER TO FOCUS ON THEIR HEALTH'	Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:52

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:16

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:52

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:16

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:52

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:16

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:52

US3042295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:16

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:11:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:59:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	23 Sep 2020 19:03:52