

US3042032 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:56:37

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US3042032

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

[Participant ID](#)

US3042032

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

US3042032

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Date of Birth (MMM yyyy)	(b) (6) 1939
Age	81
Age Units	YEARS
Age (Derived)	81
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Date of Informed Consent (dd MMM yyyy)	29 JUL 2020
Month and Year of Informed Consent (derived)	JUL 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 01 Apr 2021 13:30:14

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Condition	BILATERAL HANDS ESSENTIAL TREMOR
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Condition	CHRONIC DYSPNEA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	29 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	17:10 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 17:10
Height (<i>xxx.x</i>)	178 cm
Weight (<i>xxx.x</i>)	98 kg
BMI (<i>xxx.x</i>)	30.93044 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

PT GOES OUT TO
RESTAURANTS, GROCERY
STORES, ETC

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 01 Apr 2021 13:30:14

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

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

What was the participant's randomization number? 184054

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 13:30:14

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

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)	29 JUL 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 17:10
Temperature (xxx.x)	37.2 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

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)	29 JUL 2020
Time of assessment (00:00-23:59)	18:45 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 18:45
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 18:06 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 18:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	29 JUL 2020
Collection time (00:00-23:59)	17:48 (24 HR)
Collection date and time (derived)	29 JUL 2020 17:48

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:21	29 JUL 2020 17:21
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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

98.3 °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

29 JUL 2020 18:47

PC Open Date & Time

29 JUL 2020 18:26

PC Close Date & Time

29 JUL 2020 20:56

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 JUL 2020 21:51

PC Close Date & Time

30 JUL 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 11:16

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 13:10

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 20:04

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 13:17

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

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

99.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 19:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 18:05

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 18:48

PC Open Date & Time

29 JUL 2020 18:26

PC Close Date & Time

29 JUL 2020 20:56

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 JUL 2020 21:51

PC Close Date & Time

30 JUL 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

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

31 JUL 2020 11:16

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 13:11

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 20:05

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 13:18

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 19:57

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 18:06

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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 ☐

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 18:50
PC Open Date & Time	29 JUL 2020 18:26
PC Close Date & Time	29 JUL 2020 20:56

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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 ☐

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

29 JUL 2020 21:51

PC Close Date & Time

30 JUL 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

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 ☒

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EAB) (1725)

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US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

Yes ☐	
PC Time stamp	31 JUL 2020 11:17
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

Yes ☐	
PC Time stamp	31 JUL 2020 13:12
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

Yes ☐	
PC Time stamp	01 AUG 2020 20:05
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

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 ☒

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EAB) (1725)

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US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

Yes ☐	
PC Time stamp	02 AUG 2020 13:18
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

Yes ☐	
PC Time stamp	03 AUG 2020 19:57
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

Yes ☐	
PC Time stamp	04 AUG 2020 18:06
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3042032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042032

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042032

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042032

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

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

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

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

US3042032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3042032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Collection date (dd MMM yyyy)

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

US3042032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3042032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:56:37

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

US3042032

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:56:37

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☐

US3042032

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:56:37

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3042032

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

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

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 _____

US3042032

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:37

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		

US3042032

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

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)	_____

US3042032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:56:37

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection Date and Time (derived)

US3042032

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3042032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

AEID

Adverse event

EXACERBATION OF CHRONIC
DYSPNEA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 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)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ 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)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

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

Yes ☒

No ☐

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

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

	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 2005	
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	☒

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

	Intraocular	☐
	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

Name of Medication PRIMIDONE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL HAND ESSENTIAL
TREMOR

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

	Intraocular	☐
	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 2015	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

	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	2005
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	☒

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 13:30:13

Generated On: 09 Jun 2021 14:56:37

	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 2005	
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	☒

US3042032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Date of dosing discontinuation (dd MMM yyyy) 27 AUG 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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 01 Apr 2021 13:30:14

Generated On: 09 Jun 2021 14:56:37

Date of study discontinuation/completion (dd MMM yyyy) 27 AUG 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

US3042032 (Prod: Meridian Clinical Research)

US3042032

Form: Participant Creation

Generated On: 09 Jun 2021 14:56:37

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'US3042032'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 22:24:23

US3042032

Form: Participant Creation

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:55:25

US3042032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:38:17

US3042032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 22:24:24

US3042032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	30 Jul 2020 15:38:17
	(b) (4)	

US3042032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'SCRN'	(b) (4), (b) (6) System	30 Jul 2020 15:38:17

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered (b) (6) 1939'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 22:24:25

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '81'	Rylea Gulick (b) (4)	30 Jul 2020 15:56:13
	(b) (4)	

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'YEARS'	(b) (4), (b) (6) System	30 Jul 2020 15:56:13

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '81'	(b) (4), (b) (6)	
	System	30 Jul 2020 15:56:19
User entered empty.	System	29 Jul 2020 23:09:36

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Male (M)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:13

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:13

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '1'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:13

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:13

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:56:13
	(b) (4)	

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:13

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:56:13
	(b) (4)	

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:56:13
	(b) (4)	

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 15:56:13
	(b) (4)	

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:13

US3042032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:37

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:56:13
	(b) (4)	

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Jul 2020 15:56:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Jul 2020 15:56:19
User entered '29 Jul 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	30 Jul 2020 15:56:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 23:09:36
User entered empty.	Rylea Gulick (b) (4)	29 Jul 2020 23:09:36
	(b) (4)	

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'Jul 2020'	(b) (4), (b) (6)	
	System	30 Jul 2020 15:56:19
User entered empty.	System	29 Jul 2020 23:09:36

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '2020'	(b) (4), (b) (6)	
	System	30 Jul 2020 15:56:19
User entered empty.	System	29 Jul 2020 23:09:36

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Jul 2020 15:56:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Jul 2020 15:56:19
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	30 Jul 2020 15:56:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 23:09:36
User entered empty.	Rylea Gulick (b) (4)	29 Jul 2020 23:09:36
	(b) (4)	

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Jul 2020 23:09:36

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	29 Jul 2020 23:09:36
	(b) (4)	

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Jul 2020 23:09:36

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Jul 2020 23:09:36
	(b) (4)	

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 22:24:24

US3042032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	29 Jul 2020 23:09:40

US3042032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Jul 2020 23:09:40

US3042032

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:56:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:23

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	30 Jul 2020 15:58:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Jul 2020 15:58:08
	(b) (4)	
Data point term sent to Coder	System	30 Jul 2020 15:56:56
User entered 'HYPERTENSION'	Rylea Gulick (b) (4)	30 Jul 2020 15:56:44
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'UN UNK 2005'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:56:44
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'Jan 2005'	(b) (4), (b) (6) System	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '2005'	(b) (4), (b) (6) System	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	30 Jul 2020 15:56:44

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Jul 2020 15:59:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 15:59:10
Data point term sent to Coder	System	30 Jul 2020 15:57:58
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'UN UNK 2010'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:57:03
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 15:57:03
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'Jan 2010'	(b) (4), (b) (6) System	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '2010'	(b) (4), (b) (6) System	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	30 Jul 2020 15:57:03

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:57:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:57:19
Data point term sent to Coder	System	10 Aug 2020 19:14:27
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	10 Aug 2020 19:14:04
User entered 'BILATERAL HANDS ESSENTIAL TREMOR' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Aug 2020 19:14:04
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 15:59:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 15:59:10
Data point term sent to Coder	System	30 Jul 2020 15:57:57
User entered 'ESSENTIAL TREMOR'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'UN UNK 2015'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:57:16
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 15:57:16
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'Jan 2015'	(b) (4), (b) (6) System	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '2015'	(b) (4), (b) (6) System	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	30 Jul 2020 15:57:16

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 21:37:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 21:37:17
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 21:31:12
User entered 'chronic dyspnea'	Jessica Knight (b) (4)	02 Oct 2020 21:30:30
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'un UNK 2018'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Oct 2020 21:30:30

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Jessica Knight (b) (4)	02 Oct 2020 21:30:30
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Oct 2020 21:30:30

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	02 Oct 2020 21:30:30
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Jessica Knight (b) (4)	02 Oct 2020 21:30:30
	(b) (4)	

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'Jan 2018'	(b) (4), (b) (6) System	02 Oct 2020 21:30:30

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '2018'	(b) (4), (b) (6) System	02 Oct 2020 21:30:30

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 21:30:30

US3042032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 21:30:30

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '29 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '17:10'	Rylea Gulick (b) (4)	30 Jul 2020 15:57:54
	(b) (4)	

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '29 Jul 2020 17:10'	(b) (4), (b) (6) System	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '178' cm	(b) (4) Rylea Gulick (b) (4)	30 Jul 2020 15:57:54
DataPoint set to visible.	(b) (4) System	29 Jul 2020 23:09:40

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '98' kg	(b) (4) Rylea Gulick (b) (4)	30 Jul 2020 15:57:54
DataPoint set to visible.	(b) (4) System	29 Jul 2020 23:09:40

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
Amendment Manager: User entered '30.93044'	(b) (4), (b) (6)	
User entered '30.9'	System	16 Sep 2020 23:38:34
DataPoint set to visible.	System	30 Jul 2020 15:57:54
	System	29 Jul 2020 23:09:40

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'kg/m2'	(b) (4), (b) (6)	
	System	30 Jul 2020 15:57:54
DataPoint set to visible.	System	29 Jul 2020 23:09:40

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
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) (b) (4), (b) (6)	09 Oct 2020 03:54:09
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 13:04:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 13:04:13
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) (b) (4), (b) (6)	07 Oct 2020 14:20:53
User entered '37.2' C	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 13:04:13
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	30 Jul 2020 15:57:54
	(b) (4)	

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 13:04:13
change Data Entry Error	(b) (4)	
User entered '91'	Rylea Gulick (b) (4)	30 Jul 2020 15:57:54
	(b) (4)	

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'bpm'	(b) (4), (b) (6) System	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Rylea Gulick (b) (4)	08 Oct 2020 13:04:13
User entered '16'	(b) (4) Rylea Gulick (b) (4)	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Rylea Gulick (b) (4)	08 Oct 2020 13:04:13
User entered '152'	(b) (4) Rylea Gulick (b) (4)	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'mmHg'	(b) (4), (b) (6) System	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 13:04:13
change Data Entry Error	(b) (4)	
User entered '89'	Rylea Gulick (b) (4)	30 Jul 2020 15:57:54
	(b) (4)	

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'mmHg'	(b) (4), (b) (6) System	30 Jul 2020 15:57:54

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	

US3042032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	

US3042032

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:04

US3042032

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '29 Jul 2020'	Rylea Gulick (b) (4)	30 Jul 2020 15:58:04
	(b) (4)	

US3042032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

US3042032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

US3042032

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	30 Jul 2020 15:58:43
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'PT GOES OUT TO RESTAURANTS, GROCERY STORES, ETC'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

US3042032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '1'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 15:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 15:58:43
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:03:51

US3042032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '29 Jul 2020'	Rylea Gulick (b) (4)	30 Jul 2020 16:03:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	30 Jul 2020 16:03:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'VISIT1'	(b) (4), (b) (6) System	30 Jul 2020 16:03:51

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 22:54:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:19:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:19:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 22:54:19
User entered '184054' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 22:54:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 22:54:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:04:06

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:04:06

US3042032

Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:04:06

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:37

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:04:06

US3042032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:04:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 06:44:54
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Oct 2020 14:18:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	13 Oct 2020 14:18:53
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 12:15:28
User entered '178' cm	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	13 Oct 2020 14:18:53
change Data Entry Error	(b) (4)	
User entered '98' kg	Rylea Gulick (b) (4)	30 Jul 2020 16:05:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 06:44:54
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Oct 2020 14:18:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	13 Oct 2020 14:18:53
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 12:15:28
User entered '178' cm	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	13 Oct 2020 14:18:53
change Data Entry Error	(b) (4)	
User entered '98' kg	Rylea Gulick (b) (4)	30 Jul 2020 16:05:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '29 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '17:10'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '29 Jul 2020 17:10'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '37.2' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:05:03
	(b) (4)	

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '91'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'bpm'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '16'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '152'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'mmHg'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '89'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'mmHg'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 06:44:54
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Oct 2020 14:18:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	13 Oct 2020 14:18:53
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 12:15:28
User entered '178' cm	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	13 Oct 2020 14:18:53
change Data Entry Error	(b) (4)	
User entered '98' kg	Rylea Gulick (b) (4)	30 Jul 2020 16:05:03
	(b) (4)	

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '29 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Aug 2020 11:29:52
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL, SUBJECT ONLY NEEDS TO WAIT 30 MINUTES AFTER VACCINATION FOR POST DOSE VITALS TO BE TAKEN' (Site from System).	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:33
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		30 Jul 2020 16:05:03
User entered '18:45'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '29 Jul 2020 18:45'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '36.8' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '88'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'bpm'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '16'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '142'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'mmHg'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '88'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'mmHg'	(b) (4), (b) (6) System	30 Jul 2020 16:05:03

US3042032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:40

US3042032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '29 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:40

US3042032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Jul 2020 23:09:59

US3042032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	29 Jul 2020 23:09:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	29 Jul 2020 23:09:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '29 Jul 2020'	Rylea Gulick (b) (4)	29 Jul 2020 23:09:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '18:06'	Rylea Gulick (b) (4)	29 Jul 2020 23:09:59
	(b) (4)	

US3042032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '29 Jul 2020 18:06'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Jul 2020 23:09:59

US3042032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'ONCE'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:05:59

US3042032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '29 Jul 2020'	Rylea Gulick (b) (4)	30 Jul 2020 16:05:59
	(b) (4)	

US3042032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '17:48'	Rylea Gulick (b) (4)	30 Jul 2020 16:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '29 Jul 2020 17:48'	(b) (4), (b) (6) System	30 Jul 2020 16:05:59

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:56:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '29 Jul 2020'	Rylea Gulick (b) (4)	30 Jul 2020 16:06:16
	(b) (4)	

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:06:16

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:06:16

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '17:21'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:06:16

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '29 Jul 2020 17:21'	(b) (4), (b) (6) System	30 Jul 2020 16:06:16

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:06:16

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:06:16

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:06:16
	(b) (4)	

US3042032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	30 Jul 2020 16:06:16

US3042032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	30 Jul 2020 16:06:18
	(b) (4)	

US3042032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:06:18

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:47:02', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '527a2f6f-4547-48e0-9ea6-881d50f1d448'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	29 Jul 2020 23:47:34

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:47:10', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '527a2f6f-4547-48e0-9ea6-881d50f1d448' User entered '98.3'	(b) (4), (b) (6) System	29 Jul 2020 23:47:34
	System	29 Jul 2020 23:47:34

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:47:22', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '527a2f6f-4547-48e0-9ea6-881d50f1d448'	(b) (4), (b) (6)	
	System	29 Jul 2020 23:47:34
User entered 'No (N)'	System	29 Jul 2020 23:47:34

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:47:30', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '527a2f6f-4547-48e0-9ea6-881d50f1d448' User entered '29 Jul 2020 18:47'	(b) (4), (b) (6) System	29 Jul 2020 23:47:34
	System	29 Jul 2020 23:47:34

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 18:26'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 20:56'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 21:51'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '30 Jul 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 2'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:15:09', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '171c2a78-36c1-4d03-9949-c2676314af54' User entered 'Yes (Y)'	(b) (4), (b) (6) System	31 Jul 2020 16:16:12
	System	31 Jul 2020 16:16:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:15:53', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '171c2a78-36c1-4d03-9949-c2676314af54' User entered '96.0'	(b) (4), (b) (6) System	31 Jul 2020 16:16:12
	System	31 Jul 2020 16:16:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:03', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '171c2a78-36c1-4d03-9949-c2676314af54' User entered 'No (N)'	(b) (4), (b) (6) System	31 Jul 2020 16:16:12
	System	31 Jul 2020 16:16:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:09', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '171c2a78-36c1-4d03-9949-c2676314af54' User entered '31 Jul 2020 11:16'	(b) (4), (b) (6) System	31 Jul 2020 16:16:12
	System	31 Jul 2020 16:16:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '30 Jul 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '31 Jul 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 3'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:09:19', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3249b9d8-25e0-4114-ad5d-cdc583407eb0' User entered 'Yes (Y)'	(b) (4), (b) (6) System	31 Jul 2020 18:10:29
	System	31 Jul 2020 18:10:29

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:09:43', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3249b9d8-25e0-4114-ad5d-cdc583407eb0' User entered '96.0'	(b) (4), (b) (6) System	31 Jul 2020 18:10:29
	System	31 Jul 2020 18:10:29

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:10:02', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3249b9d8-25e0-4114-ad5d-cdc583407eb0' User entered 'No (N)'	(b) (4), (b) (6) System	31 Jul 2020 18:10:29
	System	31 Jul 2020 18:10:29

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:10:11', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3249b9d8-25e0-4114-ad5d-cdc583407eb0' User entered '31 Jul 2020 13:10'	(b) (4), (b) (6) System	31 Jul 2020 18:10:29
	System	31 Jul 2020 18:10:29

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '31 Jul 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 4'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:16', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '2b9d4088-d709-4a9d-9374-64e29ff82b09' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:08
	System	27 Aug 2020 13:41:08

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:24', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '2b9d4088-d709-4a9d-9374-64e29ff82b09' User entered '96.8'	(b) (4), (b) (6) System	27 Aug 2020 13:41:08
	System	27 Aug 2020 13:41:08

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:31', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '2b9d4088-d709-4a9d-9374-64e29ff82b09'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:08
User entered 'No (N)'	System	27 Aug 2020 13:41:08

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:36', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '2b9d4088-d709-4a9d-9374-64e29ff82b09' User entered '01 Aug 2020 20:04'	(b) (4), (b) (6) System	27 Aug 2020 13:41:08
	System	27 Aug 2020 13:41:08

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 5'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:14:00', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '909961c8-01ff-4854-85dd-2c416c54cb5b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:17:27', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '909961c8-01ff-4854-85dd-2c416c54cb5b' User entered '98.9'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:17:33', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '909961c8-01ff-4854-85dd-2c416c54cb5b'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:17:37', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '909961c8-01ff-4854-85dd-2c416c54cb5b' User entered '02 Aug 2020 13:17'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '03 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 6'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:56:22', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'c1cdf920-1ca4-4ca7-910a-7bfcc87a5aa8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:56:31', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'c1cdf920-1ca4-4ca7-910a-7bfcc87a5aa8' User entered '99.9'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:56:43', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'c1cdf920-1ca4-4ca7-910a-7bfcc87a5aa8'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:12
User entered 'No (N)'	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:56:47', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'c1cdf920-1ca4-4ca7-910a-7bfcc87a5aa8' User entered '03 Aug 2020 19:56'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '04 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 7'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:19', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'cd394e46-2c59-4aa1-af7c-d44956830eb0' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:14
	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:28', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'cd394e46-2c59-4aa1-af7c-d44956830eb0' User entered '98.5'	(b) (4), (b) (6) System	27 Aug 2020 13:41:14
	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:36', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'cd394e46-2c59-4aa1-af7c-d44956830eb0' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:14
	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:39', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'cd394e46-2c59-4aa1-af7c-d44956830eb0' User entered '04 Aug 2020 18:05'	(b) (4), (b) (6) System	27 Aug 2020 13:41:14
	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '05 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:48:26', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ef3b91ba-1568-4dd5-bb31-41b90ee98641'	(b) (4), (b) (6)	29 Jul 2020 23:48:38
User entered 'None (1)'	System	29 Jul 2020 23:48:38

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:48:22', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ef3b91ba-1568-4dd5-bb31-41b90ee98641' User entered 'No (N)'	(b) (4), (b) (6) System	29 Jul 2020 23:48:38
	System	29 Jul 2020 23:48:38

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:48:21', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ef3b91ba-1568-4dd5-bb31-41b90ee98641' User entered 'No (N)'	(b) (4), (b) (6) System	29 Jul 2020 23:48:38
	System	29 Jul 2020 23:48:38

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:48:32', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ef3b91ba-1568-4dd5-bb31-41b90ee98641' User entered 'None (1)'	(b) (4), (b) (6) System	29 Jul 2020 23:48:38
	System	29 Jul 2020 23:48:38

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:48:37', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ef3b91ba-1568-4dd5-bb31-41b90ee98641' User entered '29 Jul 2020 18:48'	(b) (4), (b) (6) System	29 Jul 2020 23:48:38
	System	29 Jul 2020 23:48:38

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 18:26'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 20:56'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 21:51'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '30 Jul 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 2'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:19', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ffd1482f-a048-4ad9-9aeb-37a5688c7496'	(b) (4), (b) (6)	
	System	31 Jul 2020 16:16:41
User entered 'None (1)'	System	31 Jul 2020 16:16:41

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:25', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ffd1482f-a048-4ad9-9aeb-37a5688c7496'	(b) (4), (b) (6)	
User entered 'No (N)'	System	31 Jul 2020 16:16:41

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:30', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ffd1482f-a048-4ad9-9aeb-37a5688c7496'	(b) (4), (b) (6)	
User entered 'No (N)'	System	31 Jul 2020 16:16:41

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:34', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ffd1482f-a048-4ad9-9aeb-37a5688c7496'	(b) (4), (b) (6)	
	System	31 Jul 2020 16:16:41
User entered 'None (1)'	System	31 Jul 2020 16:16:41

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:40', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ffd1482f-a048-4ad9-9aeb-37a5688c7496' User entered '31 Jul 2020 11:16'	(b) (4), (b) (6) System	31 Jul 2020 16:16:41
	System	31 Jul 2020 16:16:41

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '30 Jul 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '31 Jul 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 3'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:11:08', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'd18787c8-6003-46b0-8e00-4462b9ec23cb' User entered 'None (1)'	(b) (4), (b) (6) System	31 Jul 2020 18:11:56
	System	31 Jul 2020 18:11:56

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:11:17', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'd18787c8-6003-46b0-8e00-4462b9ec23cb' User entered 'No (N)'	(b) (4), (b) (6) System	31 Jul 2020 18:11:56
	System	31 Jul 2020 18:11:56

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:11:35', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'd18787c8-6003-46b0-8e00-4462b9ec23cb' User entered 'No (N)'	(b) (4), (b) (6) System	31 Jul 2020 18:11:56
	System	31 Jul 2020 18:11:56

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:11:48', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'd18787c8-6003-46b0-8e00-4462b9ec23cb'	(b) (4), (b) (6)	
	System	31 Jul 2020 18:11:56
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 18:11:56

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:11:52', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'd18787c8-6003-46b0-8e00-4462b9ec23cb' User entered '31 Jul 2020 13:11'	(b) (4), (b) (6) System	31 Jul 2020 18:11:56
	System	31 Jul 2020 18:11:56

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '31 Jul 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 4'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:41', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '81b159a3-6fe1-4cc1-9286-ecae8d815c52'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:10
User entered 'None (1)'	System	27 Aug 2020 13:41:10

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:45', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '81b159a3-6fe1-4cc1-9286-ecae8d815c52' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:10
	System	27 Aug 2020 13:41:10

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:49', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '81b159a3-6fe1-4cc1-9286-ecae8d815c52' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:10
	System	27 Aug 2020 13:41:10

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:04:52', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '81b159a3-6fe1-4cc1-9286-ecae8d815c52'	(b) (4), (b) (6)	27 Aug 2020 13:41:10
User entered 'None (1)'	System	27 Aug 2020 13:41:10

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:00', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '81b159a3-6fe1-4cc1-9286-ecae8d815c52'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:10
User entered '01 Aug 2020 20:05'	System	27 Aug 2020 13:41:10

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 5'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:17:48', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3333cc99-12ba-4285-bb23-7e9ab7b14b9a' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:17:52', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3333cc99-12ba-4285-bb23-7e9ab7b14b9a' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:17:54', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3333cc99-12ba-4285-bb23-7e9ab7b14b9a' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:17:57', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3333cc99-12ba-4285-bb23-7e9ab7b14b9a' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:03', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '3333cc99-12ba-4285-bb23-7e9ab7b14b9a' User entered '02 Aug 2020 13:18'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '03 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 6'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:56:51', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '636e7e0d-d194-41ce-a47f-2c60b0dc49c3' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:56:54', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '636e7e0d-d194-41ce-a47f-2c60b0dc49c3' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:01', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '636e7e0d-d194-41ce-a47f-2c60b0dc49c3' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:06', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '636e7e0d-d194-41ce-a47f-2c60b0dc49c3' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:09', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '636e7e0d-d194-41ce-a47f-2c60b0dc49c3' User entered '03 Aug 2020 19:57'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '04 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 7'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:43', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4b4b19b5-81d7-46ac-b128-5c17da6376b9'	(b) (4), (b) (6)	27 Aug 2020 13:41:14
User entered 'None (1)'	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:46', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4b4b19b5-81d7-46ac-b128-5c17da6376b9' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:14
	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:50', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4b4b19b5-81d7-46ac-b128-5c17da6376b9' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:14
	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:05:54', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4b4b19b5-81d7-46ac-b128-5c17da6376b9'	(b) (4), (b) (6)	27 Aug 2020 13:41:14
User entered 'None (1)'	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:00', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4b4b19b5-81d7-46ac-b128-5c17da6376b9' User entered '04 Aug 2020 18:06'	(b) (4), (b) (6) System	27 Aug 2020 13:41:14
	System	27 Aug 2020 13:41:14

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '05 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:49:27', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963' User entered 'None (0)'	(b) (4), (b) (6) System	29 Jul 2020 23:50:23
	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:49:35', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963' User entered 'None (0)'	(b) (4), (b) (6) System	29 Jul 2020 23:50:23
	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:49:41', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963' User entered 'None (0)'	(b) (4), (b) (6) System	29 Jul 2020 23:50:23
	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:49:47', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963' User entered 'None (0)'	(b) (4), (b) (6) System	29 Jul 2020 23:50:23
	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:49:51', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963' User entered 'None (0)'	(b) (4), (b) (6) System	29 Jul 2020 23:50:23
	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:50:09', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963' User entered 'None (0)'	(b) (4), (b) (6) System	29 Jul 2020 23:50:23
	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:50:18', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963'	(b) (4), (b) (6)	
	System	29 Jul 2020 23:50:23
User entered 'No (N)'	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-29T18:50:22', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '811fb879-5e48-4d35-9897-09bb19a91963' User entered '29 Jul 2020 18:50'	(b) (4), (b) (6) System	29 Jul 2020 23:50:23
	System	29 Jul 2020 23:50:23

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 18:26'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 20:56'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

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) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:42:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '29 Jul 2020 21:51'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '30 Jul 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 2'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:49', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:55', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:16:58', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:17:02', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:17:06', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:17:10', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:17:17', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered 'No (N)'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T11:17:21', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'ac407e5d-3010-4e32-9032-20181d75efe3' User entered '31 Jul 2020 11:17'	(b) (4), (b) (6) System	31 Jul 2020 16:17:24
	System	31 Jul 2020 16:17:24

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '30 Jul 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '31 Jul 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 3'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:00', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:04', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:07', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:10', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:13', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:16', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered 'None (0)'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:21', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered 'No (N)'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-07-31T13:12:24', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '6855ec14-ee04-48f9-bbf9-5df6fd5962a5' User entered '31 Jul 2020 13:12'	(b) (4), (b) (6) System	31 Jul 2020 18:12:29
	System	31 Jul 2020 18:12:29

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '31 Jul 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 4'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:04', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:07', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:14', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:16', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:19', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:22', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:27', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-01T20:05:31', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: 'dad1a328-e880-45b2-8871-436453d13ab9' User entered '01 Aug 2020 20:05'	(b) (4), (b) (6) System	27 Aug 2020 13:41:09
	System	27 Aug 2020 13:41:09

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 5'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:08', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:11', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:15', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:18', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:21', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:24', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:29', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-02T13:18:35', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '4ed86ce2-b072-4349-97a1-bc0cb875258c' User entered '02 Aug 2020 13:18'	(b) (4), (b) (6) System	27 Aug 2020 13:41:11
	System	27 Aug 2020 13:41:11

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '03 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 6'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:13', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:12
User entered 'None (0)'	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:20', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
User entered 'None (0)'	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:23', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:28', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:30', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:12
User entered 'None (0)'	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:33', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:12
User entered 'None (0)'	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:37', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95'	(b) (4), (b) (6)	
	System	27 Aug 2020 13:41:12
User entered 'No (N)'	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-03T19:57:41', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '82dea468-6a67-4fb7-90c7-c4bf01d5da95'	(b) (4), (b) (6) System	27 Aug 2020 13:41:12
User entered '03 Aug 2020 19:57'	System	27 Aug 2020 13:41:12

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '04 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
	(b) (4), (b) (6)	
Data entry locked.	System	29 Jul 2020 23:09:59
User entered 'Day 7'	System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:04', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:07', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:10', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:13', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:16', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:19', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

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 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:23', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F57BA1B-5FA9-4B84-B14C-34B41E77BE7A)', Time: '2020-08-04T18:06:27', User OID: 'PatientReportedOutcome (US3042032)', ODM File OID: '7ba9ed40-ce2f-415b-ae37-d2cad77680d' User entered '04 Aug 2020 18:06'	(b) (4), (b) (6) System	27 Aug 2020 13:41:15
	System	27 Aug 2020 13:41:15

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:42:12
User entered '05 Aug 2020 11:59'	(b) (4), (b) (6) System	29 Jul 2020 23:09:59

US3042032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Aug 2020 16:25:10

US3042032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
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) (b) (4), (b) (6)	14 Aug 2020 14:16:31
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 'SUBJECT WAS CALLED 8/7/2020 AND MESSAGE WAS LEFT. SUBJECT WAS REACHED 8/10/2020' (Site from System).	Rylea Gulick (b) (4) (b) (4)	11 Aug 2020 16:25:46
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	11 Aug 2020 16:25:10
User entered '10 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	11 Aug 2020 16:25:10

US3042032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Aug 2020 16:25:10

US3042032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Aug 2020 16:25:10

US3042032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Aug 2020 16:25:50

US3042032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 16:25:50

US3042032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 18:23:08

US3042032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '13 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 18:23:08

US3042032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 18:23:08

US3042032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 18:23:08

US3042032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 18:23:11

US3042032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 18:23:11

US3042032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:08:52

US3042032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:08:52

US3042032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:08:52

US3042032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:08:52

US3042032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:09:31

US3042032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	27 Aug 2020 18:09:31

US3042032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: Please complete the remaining pages in this folder as these are not to remain empty. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 09:15:05
Query 'Per CDM: Please complete the remaining pages in this folder as these are not to remain empty. Thank you. ' answered with 'completed requested pages' (Site from DM).	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:58:24
User opened query 'Per CDM: Please complete the remaining pages in this folder as these are not to remain empty. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Nov 2020 13:08:22
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:09:54

US3042032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	27 Aug 2020 18:09:54
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	27 Aug 2020 18:09:54
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered 'VISIT2'	(b) (4), (b) (6) System	27 Aug 2020 18:09:54

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4)	23 Nov 2020 19:54:33
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:54:33

US3042032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:54:45

US3042032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:54:45
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:56:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	23 Nov 2020 19:57:09
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:57:09
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	23 Nov 2020 19:56:25
User entered empty.	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:56:25

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:56:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:56:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:56:25
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:56:25
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:56:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:56:25

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:56:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:56:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:57:15

US3042032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:57:15
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:57:15
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:57:15

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:56:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:57:25
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:57:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:57:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:57:25
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:57:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:57:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:57:25

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	23 Nov 2020 19:57:25
	(b) (4)	

US3042032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	23 Nov 2020 19:57:25

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Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:10:02

US3042032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 18:10:02

US3042032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:56:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	08 Sep 2020 18:42:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:00:06
Reviewed for Data Management.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 19:59:54
User closed query 'Per MM: please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 04:25:21
User closed query 'Per DM CLR: Please confirm the AE term "WORSENING OF CHRONIC DYSPNEA", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 13:24:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea exacerbated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:45:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:45:38
Query 'Per MM: please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection. ' answered with 'patient withdrew due to AE/new health concerns' (Site from DM).	Jessica Knight (b) (4) (b) (4)	02 Oct 2020 21:32:43
Data point term sent to Coder	System	02 Oct 2020 21:30:11
User entered 'EXACERBATION OF CHRONIC DYSPnea' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	02 Oct 2020 21:29:34
Data point term sent to Coder	System	02 Oct 2020 21:28:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please confirm the AE term "WORSENING OF CHRONIC DYSPNEA", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'term changed to "Exacerbation of chronic dyspnea". Please supply code/term. patient has chronic dyspnea in medical history - AE is not Dyspnea, it is for the exacerbation of ' (Site from DM). Coding entries removed.	Jessica Knight (b) (4) (b) (4)	02 Oct 2020 21:27:59
User entered 'exacerbation OF CHRONIC DYSPHEA' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	02 Oct 2020 21:27:53
User opened query 'Per MM: please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 10:55:31
User opened query 'Per DM CLR: Please confirm the AE term "WORSENING OF CHRONIC DYSPNEA", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 11:40:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 05:43:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 05:43:37
Data point term sent to Coder	System	08 Sep 2020 18:44:27
User entered 'WORSENING OF CHRONIC DYSPHEA'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '27 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or confirm the AE is ongoing, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	31 Jan 2021 10:35:31
Query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or confirm the AE is ongoing, else clarify. ' answered with 'STOP DATE IS UNKNOWN AS SUBJECT WAS DISCONTINUED FROM STUDY DUE TO THIS AE.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 23:29:23
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Jan 2021 14:46:34
' (Site from DM).		
User opened query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or confirm the AE is ongoing, else clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Jan 2021 14:46:33
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 15:47:08
' answered with 'AE WILL BE REVIEWED AND UPDATED IF NECESSARY' (Site from DM).		
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Jan 2021 04:11:43
' (Site from DM).		
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 18:43:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 18:43:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per DM CLR: RQ: Response noted, however, a worsening of a Medical History condition should have a grade of greater than 1/Mild. Review if this is a worsening of the baseline condition. If not, consider deleting this entry. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	31 Jan 2021 10:35:17
Query 'Per DM CLR: RQ: Response noted, however, a worsening of a Medical History condition should have a grade of greater than 1/Mild. Review if this is a worsening of the baseline condition. If not, consider deleting this entry. Otherwise, clarify.' answered with 'WILL BE REVIEWED, STILL GRADE 1 PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 15:47:30
User opened query 'Per DM CLR: RQ: Response noted, however, a worsening of a Medical History condition should have a grade of greater than 1/Mild. Review if this is a worsening of the baseline condition. If not, consider deleting this entry. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Jan 2021 03:38:19
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 11:59:13
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' answered with 'GRADE 1 PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 15:04:48
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Dec 2020 11:24:05

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:52:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 15:52:29
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 15:52:29
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:43:32
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 18:43:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	(b) (4) System	10 Sep 2020 23:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:52:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 15:52:29
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:52:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 15:52:29
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:43:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:52:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 15:52:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 15:52:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:43:32
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 18:43:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea; however, the event is not recorded as IP Withdrawn. Please consider updating to IP Withdrawn.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 09:06:21
Query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea; however, the event is not recorded as IP Withdrawn. Please consider updating to IP Withdrawn.' answered with 'confirmed and updated' (Site from DM).	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:08:28
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:07:58
User opened query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea; however, the event is not recorded as IP Withdrawn. Please consider updating to IP Withdrawn.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 11:09:37
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 04:12:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Meagan Miller (b) (4) (b) (4)	10 Sep 2020 23:12:21
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'ENTRY WILL BE UPDATED' (Site from System).	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:44:26
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:43:32

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '1'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

US3042032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

US3042032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

US3042032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:43:32

US3042032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '0'	(b) (4), (b) (6) System	08 Sep 2020 18:43:32

US3042032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 18:43:32

US3042032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:55:25

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:56:37

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:06:23

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Jul 2020 16:09:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jul 2020 16:09:04
Data point term sent to Coder User entered 'LOSARTAN'	System Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:08:00 30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'HYPERTENSION'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:07:17
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Aug 2020 13:34:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATIONS ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	30 Jul 2020 16:07:17
User entered 'UN UNK 2005'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:07:17
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '804 (804)'	(b) (4), (b) (6) System	30 Jul 2020 16:07:17

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	30 Jul 2020 16:13:12
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	30 Jul 2020 16:13:12
Data point term sent to Coders	System	30 Jul 2020 16:12:02
User entered 'OMEPRAZOLE'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	01 Apr 2021 13:30:15
User entered '40'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'twice daily (BID)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Aug 2020 13:34:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATIONS ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	30 Jul 2020 16:11:14
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:11:14
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '2'	(b) (4), (b) (6) System	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '804 (804)'	(b) (4), (b) (6) System	30 Jul 2020 16:11:14

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BARBITURATES AND DERIVATIVES, PRODUCT: PRIMIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:40:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:40:58
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 15:54:06 10 Sep 2020 15:53:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BARBITURATES AND DERIVATIVES, PRODUCT: PRIMIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jul 2020 21:53:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jul 2020 21:53:19
Data point term sent to Coder	System	30 Jul 2020 16:12:01
User entered 'PRIMIDONE'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 04:40:20
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 04:39:31
User closed query 'Per DM CLR: Please update the indication to reflect the location of ESSENTIAL TREMOR (e.g. bilateral hands, etc.). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 07:27:27
Query 'Per DM CLR: Please update the indication to reflect the location of ESSENTIAL TREMOR (e.g. bilateral hands, etc.). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 15:53:11
User entered 'BILATERAL HAND ESSENTIAL TREMOR' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 15:53:08
User opened query 'Per DM CLR: Please update the indication to reflect the location of ESSENTIAL TREMOR (e.g. bilateral hands, etc.). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Sep 2020 21:03:12
User entered 'ESSENTIAL TREMOR'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '50'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered 'twice daily (BID)'	Rylea Gulick (b) (4)	30 Jul 2020 16:11:49
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATIONS ONGOING' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Aug 2020 13:34:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:56
User entered 'UN UNK 2015'	System	30 Jul 2020 16:11:49
	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:11:49
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '2'	(b) (4), (b) (6) System	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '804 (804)'	(b) (4), (b) (6) System	30 Jul 2020 16:11:49

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Jul 2020 16:14:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jul 2020 16:14:13
Data point term sent to Coder User entered 'METOPROLOL'	System Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:13:02 30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'HYPERTENSION'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '25'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Aug 2020 13:34:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATIONS ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	30 Jul 2020 16:12:22
User entered 'UN UNK 2005'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:12:22
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '804 (804)'	(b) (4), (b) (6) System	30 Jul 2020 16:12:22

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Jul 2020 16:36:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Jul 2020 16:36:11
Data point term sent to Coder	System	30 Jul 2020 16:13:02
User entered 'FINASTERIDE'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 04:24:58
Query 'Per MM, Please revise the indication ' answered with 'THIS IS THE INDICATION THAT WAS PROVIDED BY THE SUBJECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 20:31:16
User opened query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 17:16:36
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '5'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Aug 2020 13:34:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATIONS ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	30 Jul 2020 16:12:51
User entered 'UN UNK 2005'	Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	30 Jul 2020 16:12:51
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	01 Apr 2021 13:30:15
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	30 Jul 2020 16:12:51
	(b) (4)	

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '1'	(b) (4), (b) (6) System	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User entered '804 (804)'	(b) (4), (b) (6) System	30 Jul 2020 16:12:51

US3042032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:56:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Jul 2020 16:13:27

US3042032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:37

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '27 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:14:40

US3042032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:37

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea. Please consider updating reason for discontinuation to AE; and record AE record number' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 09:07:54
Query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea. Please consider updating reason for discontinuation to AE; and record AE record number' answered with 'confirmed and updated' (Site from DM).	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:52:25
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:52:09
User opened query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea. Please consider updating reason for discontinuation to AE; and record AE record number' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 11:12:04
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:14:40

US3042032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:37

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)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. AE #1).' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 08:52:45
Query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. AE #1).' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 21:54:26
User entered 'AE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 21:54:13
User opened query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 19:12:49
User closed query 'Per CDM: Please note that only the record number is to be recorded in this field. The AE name is not required. Kindly update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Nov 2020 06:42:55
Query 'Per CDM: Please note that only the record number is to be recorded in this field. The AE name is not required. Kindly update as appropriate.' answered with 'corrected' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	25 Nov 2020 21:24:08
User entered 'AE 1' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	25 Nov 2020 21:23:47
User opened query 'Per CDM: Please note that only the record number is to be recorded in this field. The AE name is not required. Kindly update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 09:07:53
User entered 'AE 1- chronic dyspnea' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:52:09
User closed query 'Per CDM Please note the event of Dyspnea has not been reported in AE forms/ MH, Kindly update the appropriate forms.thanks ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Sep 2020 04:05:17
Query 'Per CDM Please note the event of Dyspnea has not been reported in AE forms/ MH, Kindly update the appropriate forms.thanks ' answered with 'DYSPNEA HAS BEEN REPORTED AS AE' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 18:44:47

US3042032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
User opened query 'Per CDM Please note the event of Dyspnea has not been reported in AE forms/ MH, Kindly update the appropriate forms.thanks ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Sep 2020 07:02:24
User entered 'PHYSICIAN DECISION TO DISCONTINUE PATIENT FROM THE STUDY AS DYSPNEA HAS WORSENERD AND PATIENT HAS STARTED TO EXPERIENCE INTERMITTENT CHEST PAINS.'	Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:14:40

US3042032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered '27 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:15:16

US3042032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:37

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea. Please consider updating reason for discontinuation to AE; and record AE record number' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 09:31:18
Query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea. Please consider updating reason for discontinuation to AE; and record AE record number' answered with 'confirmed and corrected ' (Site from DM).	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:37:45
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:31:31
User opened query 'Per CDM: per End of Study form subject discontinued due to PI decision related to worsened Dyspnea. Please consider updating reason for discontinuation to AE; and record AE record number' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 11:12:19
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:15:16

US3042032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:37

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)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User closed query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. AE #1).' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 08:54:26
Query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. AE #1).' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 21:54:48
User entered 'AE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 21:54:44
User opened query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 19:13:06
User entered 'AE 1' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:37:30
User entered 'PHYSICIAN DECISION TO DISCONTINUE PATIENT FROM THE STUDY Due to AE of DYSPNEA HAS WORSENER AND PATIENT HAS STARTED TO EXPERIENCE INTERMITTENT CHEST PAINS.' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 19:31:31
User entered 'PHYSICIAN DECISION TO DISCONTINUE PATIENT FROM THE STUDY AS DYSPNEA HAS WORSENER AND PATIENT HAS STARTED TO EXPERIENCE INTERMITTENT CHEST PAINS.'	Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:15:16

US3042032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:37

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:15:16

US3042032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:37

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:15:16

US3042032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:37

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:15:16

US3042032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:37

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:55:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	01 Apr 2021 13:30:15
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:15:16