

US3442074 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:41:42

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US3442074

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:55:16

Generated On: 09 Jun 2021 17:41:42

[Participant ID](#)

US3442074

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

US3442074

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 AUG 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) 23 Feb 2021 18:55:17

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Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:55:17

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Date of Informed Consent (<i>dd MMM yyyy</i>)	25 AUG 2020
Month and Year of Informed Consent (<i>derived</i>)	AUG 2020
Year of Informed Consent (<i>derived</i>)	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

US3442074

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:55:17

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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) 23 Feb 2021 18:55:17

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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) 23 Feb 2021 18:55:17

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Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Condition	HOT FLASHES
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442074

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	25 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:20 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 08:20
Height (<i>xxx.x</i>)	69.0 in
Weight (<i>xxx.x</i>)	137.4 lb
BMI (<i>xxx.x</i>)	20.33286 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) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 18:55:17

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Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2012

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:55:17

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:55:17

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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) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 AUG 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) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 144739

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

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

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

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

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

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

Liver Disease Yes ☐
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

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) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

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)	25 AUG 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 08:20
Temperature (xxx.x)	98.9 F
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)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

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)	25 AUG 2020
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:11
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 09:35 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 09:35

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) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	25 AUG 2020
Collection time (00:00-23:59)	08:58 (24 HR)
Collection date and time (derived)	25 AUG 2020 08:58

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:52	25 AUG 2020 08:52
Nasopharyngeal Swab 2	No		

US3442074

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 10:17

PC Open Date & Time

25 AUG 2020 09:55

PC Close Date & Time

25 AUG 2020 12:25

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	25 AUG 2020 17:25
PC Open Date & Time	25 AUG 2020 13:20
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

26 AUG 2020 17:07

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 17:05

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 17:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 17:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 17:00

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 17:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 10:17

PC Open Date & Time

25 AUG 2020 09:55

PC Close Date & Time

25 AUG 2020 12:25

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 17:25

PC Open Date & Time

25 AUG 2020 13:20

PC Close Date & Time

26 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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

26 AUG 2020 17:08

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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

27 AUG 2020 17:05

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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

28 AUG 2020 17:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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

29 AUG 2020 17:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

30 AUG 2020 17:00

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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

31 AUG 2020 17:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 ☐

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 10:18
PC Open Date & Time	25 AUG 2020 09:55
PC Close Date & Time	25 AUG 2020 12:25

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 ☐

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 17:26
PC Open Date & Time	25 AUG 2020 13:20
PC Close Date & Time	26 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

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)

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	26 AUG 2020 17:08
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 1675

EAB) (1725)

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	27 AUG 2020 17:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 1675

EAB) (1725)

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	28 AUG 2020 17:08
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 1675

EAB) (1725)

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	29 AUG 2020 17:03
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 ☒

PRODUCTION RELEASE (v12.003

55 of 1675

EAB) (1725)

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	30 AUG 2020 17:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

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

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EAB) (1725)

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	31 AUG 2020 17:15
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3442074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	08:23 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 08:23
Temperature (xxx.x)	97.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 09:59
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3442074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 09:24 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 09:24

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

US3442074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

22 SEP 2020 08:40

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:43	22 SEP 2020 08:43
Nasopharyngeal Swab 2	No		

US3442074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

97.9 °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

22 SEP 2020 09:58

PC Open Date & Time

22 SEP 2020 09:44

PC Close Date & Time

22 SEP 2020 12:14

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐
No ☒

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

PC Time Stamp	22 SEP 2020 18:11
PC Open Date & Time	22 SEP 2020 13:09
PC Close Date & Time	23 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

23 SEP 2020 17:09

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

24 SEP 2020 19:42

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:17

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 17:22

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 18:14

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

28 SEP 2020 17:15

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 09:59

PC Open Date & Time

22 SEP 2020 09:44

PC Close Date & Time

22 SEP 2020 12:14

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 18:12

PC Open Date & Time

22 SEP 2020 13:09

PC Close Date & Time

23 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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

23 SEP 2020 17:10

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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

24 SEP 2020 19:43

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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

25 SEP 2020 18:18

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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

26 SEP 2020 17:22

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

27 SEP 2020 18:14

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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

28 SEP 2020 17:15

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 ☐

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 10:00
PC Open Date & Time	22 SEP 2020 09:44
PC Close Date & Time	22 SEP 2020 12:14

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 ☐

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 18:12
PC Open Date & Time	22 SEP 2020 13:09
PC Close Date & Time	23 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

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 ☒

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	23 SEP 2020 17:10
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	24 SEP 2020 19:43
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	25 SEP 2020 18:18
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	26 SEP 2020 17:23
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	27 SEP 2020 18:14
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

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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US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

Yes ☐	
PC Time stamp	28 SEP 2020 17:16
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3442074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

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.

US3442074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

08:32 (24 HR)

Collection date and time (derived)

23 OCT 2020 08:32

US3442074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:18

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 17:59:11

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 12:01:38
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 10:32:29

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 11:09:24

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 09:01:08

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 12:23:15

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 14:58:01

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 11:29:43

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 10:35:26

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 15:41:46

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 12:08:36

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 14:59:44
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 18:23:51

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 14:18:42

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 13:17:28
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 20:11:59

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

DAY 215

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 10:43:59
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3442074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:41:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 14:19:06

US3442074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:19:53

Generated On: 09 Jun 2021 17:41:42

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

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.

US3442074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3442074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442074

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:41:42

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 ☐

US3442074

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:41:42

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3442074

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	19 JAN 2021

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

Folder OID	UNBLND_DECIDE

US3442074

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3442074

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Height	
Weight	
BMI (xxx.x)	

US3442074

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	08:43 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 08:43
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3442074

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:05
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3442074

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3442074

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 09:33 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 09:33

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

US3442074

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	19 JAN 2021

Collection time (00:00-23:59)	08:47 (24 HR)

Collection date and time (derived)	19 JAN 2021 08:47

US3442074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	08:49
Collection Date and Time (derived)	19 JAN 2021 08:49

US3442074

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?	Yes ☒
	No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

US3442074

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 10:00
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 11:08
Temperature (xxx.x)	99.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3442074

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3442074

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 FEB 2021

What was the treatment time? (00:00-23:59) 10:28 (24 HR)

Treatment Date and Time (derived) 22 FEB 2021 10:28

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

US3442074

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442074

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:35:11

Generated On: 09 Jun 2021 17:41:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442074

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 15:19:53

Generated On: 09 Jun 2021 17:41:42

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD57

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:19:53

Generated On: 09 Jun 2021 17:41:42

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	08:37 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 08:37
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3442074

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 15:19:53

Generated On: 09 Jun 2021 17:41:42

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.

US3442074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 15:19:53

Generated On: 09 Jun 2021 17:41:42

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3442074

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

AEID	
Adverse event	NAUSEA
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)	26 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

AEID	USA-US017-2021-MRNA-1273-P30 1000010
Adverse event	ISCHEMIC CEREBROVASCULAR ACCIDENT (CVA) (HCC)
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)	02 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	06 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 APR 2021
Hospital Discharge Date (dd MMM yyyy)	06 APR 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

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	SUBJECT SUFFERED FROM A STROKE ON 02APR021 AND WAS HOSPITALIZED. SUBJECT PASSED AWAY ON 06APR2021. MEDICAL RECORDS HAVE BEEN REQUESTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

AEID	USA-US017-2021-MRNA-1273-P30 1000011
Adverse event	DIABETIC KETOACIDOSIS
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)	UN MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	UN MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	UN MAR 2021
Hospital Discharge Date (dd MMM yyyy)	UN MAR 2021
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

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	

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

DURING REVIEW OF MEDICAL
RECORDS FOR SAE "STROKE",
THE FOLLOWING WAS NOTED:
"PATIENT WAS RECENTLY
ADMITTED A FEW WEEKS AGO
TO ANOTHER HOSPITAL FOR
DKA, WHICH REQUIRED ICU
ADMISSION." THE SUBJECT IS
NOW DECEASED AND WE HAVE
NO OTHER INFORMATION
REGARDING HOSPITAL AND/OR
TIMELINES OF EVENT.

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

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

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

Yes ☒

No ☐

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

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 750

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 (1)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

	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 2009
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 (2)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Name of Medication SYMBICORT

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 2

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 (2)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

	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 2013	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Name of Medication BENICAL/HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40/25

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

200 of 1675

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3442074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:55:17

Generated On: 09 Jun 2021 17:41:42

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 13 Apr 2021 15:19:53

Generated On: 09 Jun 2021 17:41:42

Date of study discontinuation/completion (dd MMM yyyy) 06 APR 2021

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

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) 06 APR 2021

Was autopsy performed?

Yes	☐
No	☐
Unknown	☒

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 23:22:55

Generated On: 09 Jun 2021 17:41:42

SAEID	USA-US017-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 23:22:55

Generated On: 09 Jun 2021 17:41:42

SAEID	USA-US017-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/APR/2021 11:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 23:22:55

Generated On: 09 Jun 2021 17:41:42

SAEID	USA-US017-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 14:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 23:22:55

Generated On: 09 Jun 2021 17:41:42

SAEID	USA-US017-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/APR/2021 08:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 23:22:55

Generated On: 09 Jun 2021 17:41:42

SAEID	USA-US017-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	29/APR/2021 10:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 23:22:55

Generated On: 09 Jun 2021 17:41:42

SAEID	USA-US017-2021-MRNA-1273-P301000011
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 23:22:55

Generated On: 09 Jun 2021 17:41:42

SAEID	USA-US017-2021-MRNA-1273-P301000011
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/APR/2021 11:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3442074 (Prod: Benchmark Research - Fort Worth)

US3442074

Form: Participant Creation

Generated On: 09 Jun 2021 17:41:42

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 04:53:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'US3442074'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 12:59:41

US3442074

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (u), (+), (b) (6)	17 Sep 2020 20:19:11
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:24

US3442074

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Sep 2020 20:19:13
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 12:59:42

US3442074

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:19:15
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:24

US3442074

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'SCRN'	System	25 Aug 2020 14:32:24

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:19:53
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 12:59:43

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:19:55
User entered '61'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'YEARS'	System	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '61'	System	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:19:58
User entered 'Female (F)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:16
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:19
User entered '1'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:30
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:30
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:30
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:30
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:30
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:30
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:30
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:32:51

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:24:57
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'Aug 2020'	System	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '2020'	System	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:24:59
User entered 'Amendment 3 (3)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:26:35
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:26:37
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:26:39
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:27:12
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:10

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:27:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 12:59:42

US3442074

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '1'	System	25 Aug 2020 14:33:15

US3442074

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:30:57
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:15

US3442074

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:41:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:33:53
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:20

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:35:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:35:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:35:33
Data point term sent to Coder	System	25 Aug 2020 16:34:58
User entered 'TYPE II DIABETES'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:35:42
User entered 'UN UNK 2009'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:35:45
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:35:47
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:35:50
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:35:53
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'Jan 2009'	System	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '2009'	System	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:33:56

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:03
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:35:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:35:33
Data point term sent to Coder	System	25 Aug 2020 16:34:58
User entered 'POST MENOPAUSAL'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:05
User entered 'UN UNK 2012'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:06
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:18
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:21
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'Jan 2012'	System	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '2012'	System	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:34:21

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:47
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:35:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:35:33
Data point term sent to Coder	System	25 Aug 2020 16:34:58
User entered 'HOT FLASHES'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:49
User entered 'UN UNK 2012'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:51
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:53
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:55
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:36:56
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'Jan 2012'	System	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '2012'	System	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:34:39

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:17
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:36:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:36:34
Data point term sent to Coder	System	25 Aug 2020 16:35:59
User entered 'HYPERTENSION'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:19
User entered 'UN UNK 2014'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:22
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:24
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:26
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:28
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'Jan 2014'	System	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '2014'	System	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:35:12

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:36:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:36:35
Data point term sent to Coder	System	25 Aug 2020 16:36:00
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:44
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:46
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:47
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:49
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:37:51
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'Jan 2013'	System	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '2013'	System	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:35:53

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:46:31
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:46:32
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:46:41
User entered '08:20'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '25 Aug 2020 08:20'	System	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:46:44
User entered '69.0' in	Melody Dufrene (b) (4)	25 Aug 2020 16:29:57
DataPoint set to visible.	(b) (4) System	25 Aug 2020 14:33:15

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:46:54
User entered '137.4' lb	Melody Dufrene (b) (4)	25 Aug 2020 16:29:57
DataPoint set to visible.	(b) (4) System	25 Aug 2020 14:33:15

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
Amendment Manager: User entered '20.33286'	System	17 Sep 2020 00:22:18
User entered '20.3'	System	25 Aug 2020 16:29:57
DataPoint set to visible.	System	25 Aug 2020 14:33:15

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'kg/m2'	System	25 Aug 2020 16:29:57
DataPoint set to visible.	System	25 Aug 2020 14:33:15

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:47:01
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:47:01
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:47:01
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:47:01
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'bpm'	System	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Sep 2020 20:47:01
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'breaths/min'	System	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:47:01
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'mmHg'	System	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:47:01
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'mmHg'	System	25 Aug 2020 16:29:57

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28

US3442074

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28

US3442074

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:48:02
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:06

US3442074

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:50:35
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:06

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:50:55
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:50:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:51:28
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:51:35
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:51:35
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:51:35
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:51:35
User entered 'UN UNK 2012'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:51:35
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:30:40

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (U) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered '1'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 16:31:28
	(b) (4)	

US3442074

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:53:22
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:28

US3442074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Sep 2020 20:56:51
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:29

US3442074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:53
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:29

US3442074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:57
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:29

US3442074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'VISIT1'	System	25 Aug 2020 14:33:29

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:54:27
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 14:14:40

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:54:30
User entered '144739'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 14:14:40

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:55:08
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 14:14:40

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:02
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:59

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:03
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:59

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:13
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:59

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:17
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:59

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:21
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:33:59

US3442074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
DataPoint Verified.		08 Apr 2021 04:53:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	22 Sep 2020 22:18:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:47:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:47:53

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:57:34
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:57:35
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:57:34
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:57:35
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:07
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:09
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:12
User entered '08:20'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '25 Aug 2020 08:20'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:15
User entered '98.9' F	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:21
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:24
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:36
User entered '91'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'bpm'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:44
User entered '16'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'breaths/min'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:58:54
User entered '118'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'mmHg'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:59:00
User entered '74'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'mmHg'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:57:34
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:57:35
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User accepted default value 'Post-Dose (POSTDOSE)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:00:20
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:00:23
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:00:48
User entered '10:11'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '25 Aug 2020 10:11'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:29
User entered '98.6' F	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:30
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:34
User entered '91'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'bpm'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:37
User entered '12'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'breaths/min'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:41
User entered '135'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'mmHg'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:42
User entered '83'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'mmHg'	System	25 Aug 2020 16:38:04

US3442074

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:54
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:44

US3442074

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:34:56
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:31:44

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:35:10
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:35:35
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:35:38
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:35:45
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:35:47
User entered '09:35'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '25 Aug 2020 09:35'	System	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:35:50
User entered 'Left Arm (LEFT ARM)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
DataPoint Verified.		17 Sep 2020 21:35:51
User entered 'ONCE'	System	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 14:40:40

US3442074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:37:17
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:32:51

US3442074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:37:20
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:32:51

US3442074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:37:22
User entered '08:58'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:32:51

US3442074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '25 Aug 2020 08:58'	System	25 Aug 2020 16:32:51

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:37:27
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:37:37
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:37:40
User entered '08:52'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '25 Aug 2020 08:52'	System	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:37:44
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:53
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered empty.	System	25 Aug 2020 16:33:05

US3442074

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:38:46
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:33:11

US3442074

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User entered '1'	System	25 Aug 2020 16:33:11

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:05', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ac8ac4b-6a4e-4914-9cca-3eec3f563e69' User entered 'Yes (Y)'	System	25 Aug 2020 15:17:39
	System	25 Aug 2020 15:17:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:16:50', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ac8ac4b-6a4e-4914-9cca-3eec3f563e69' User entered '98.7'	System	25 Aug 2020 15:17:39
	System	25 Aug 2020 15:17:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:10', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ac8ac4b-6a4e-4914-9cca-3eec3f563e69' User entered 'No (N)'	System	25 Aug 2020 15:17:39
	System	25 Aug 2020 15:17:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ac8ac4b-6a4e-4914-9cca-3eec3f563e69' User entered '25 Aug 2020 10:17'	System	25 Aug 2020 15:17:39
	System	25 Aug 2020 15:17:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 09:55'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 12:25'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:24:55', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7b658a80-3b7b-4bd6-94f5-059f36babcbc' User entered 'Yes (Y)'	System	25 Aug 2020 22:25:24
	System	25 Aug 2020 22:25:24

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:06', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7b658a80-3b7b-4bd6-94f5-059f36babcbc' User entered '97.5'	System	25 Aug 2020 22:25:24
	System	25 Aug 2020 22:25:24

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:12', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7b658a80-3b7b-4bd6-94f5-059f36babcbc' User entered 'No (N)'	System	25 Aug 2020 22:25:24
	System	25 Aug 2020 22:25:24

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:19', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7b658a80-3b7b-4bd6-94f5-059f36babcbc' User entered '25 Aug 2020 17:25'	System	25 Aug 2020 22:25:24
	System	25 Aug 2020 22:25:24

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 13:20'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 2'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:07:26', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f4eb1617-327d-42af-8123-b9464f9c43f9' User entered 'Yes (Y)'	System	26 Aug 2020 22:07:51
	System	26 Aug 2020 22:07:51

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:07:38', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f4eb1617-327d-42af-8123-b9464f9c43f9' User entered '97.8'	System	26 Aug 2020 22:07:51
	System	26 Aug 2020 22:07:51

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:07:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f4eb1617-327d-42af-8123-b9464f9c43f9'	System	26 Aug 2020 22:07:51
User entered 'No (N)'	System	26 Aug 2020 22:07:51

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:07:48', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f4eb1617-327d-42af-8123-b9464f9c43f9' User entered '26 Aug 2020 17:07'	System	26 Aug 2020 22:07:51
	System	26 Aug 2020 22:07:51

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 3'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:04:53', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '74eb77a4-79bc-4df3-97ff-13f663249952'	System	27 Aug 2020 22:05:39
User entered 'Yes (Y)'	System	27 Aug 2020 22:05:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '74eb77a4-79bc-4df3-97ff-13f663249952'	System	27 Aug 2020 22:05:39
User entered '97.8'	System	27 Aug 2020 22:05:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:28', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '74eb77a4-79bc-4df3-97ff-13f663249952'	System	27 Aug 2020 22:05:39
User entered 'No (N)'	System	27 Aug 2020 22:05:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:34', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '74eb77a4-79bc-4df3-97ff-13f663249952'	System	27 Aug 2020 22:05:39
User entered '27 Aug 2020 17:05'	System	27 Aug 2020 22:05:39

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 4'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:07', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '28b396a7-8412-41ab-b7fb-0a36b332b388' User entered 'Yes (Y)'	System	28 Aug 2020 22:07:29
	System	28 Aug 2020 22:07:29

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:15', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '28b396a7-8412-41ab-b7fb-0a36b332b388' User entered '97.8'	System	28 Aug 2020 22:07:29
	System	28 Aug 2020 22:07:29

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '28b396a7-8412-41ab-b7fb-0a36b332b388' User entered 'No (N)'	System	28 Aug 2020 22:07:29
	System	28 Aug 2020 22:07:29

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:26', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '28b396a7-8412-41ab-b7fb-0a36b332b388' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 22:07:29
	System	28 Aug 2020 22:07:29

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 5'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:15', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '003093e1-1a70-45dd-ace7-7f8b655a5ca7' User entered 'Yes (Y)'	System	29 Aug 2020 22:02:36
	System	29 Aug 2020 22:02:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '003093e1-1a70-45dd-ace7-7f8b655a5ca7' User entered '97.8'	System	29 Aug 2020 22:02:36
	System	29 Aug 2020 22:02:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '003093e1-1a70-45dd-ace7-7f8b655a5ca7'	System	29 Aug 2020 22:02:36
User entered 'No (N)'	System	29 Aug 2020 22:02:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:32', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '003093e1-1a70-45dd-ace7-7f8b655a5ca7' User entered '29 Aug 2020 17:02'	System	29 Aug 2020 22:02:36
	System	29 Aug 2020 22:02:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 6'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:13', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ee965363-5107-4c93-bf7d-fdf8d16987c1' User entered 'Yes (Y)'	System	30 Aug 2020 22:00:36
	System	30 Aug 2020 22:00:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:21', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ee965363-5107-4c93-bf7d-fdf8d16987c1' User entered '97.7'	System	30 Aug 2020 22:00:36
	System	30 Aug 2020 22:00:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:26', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ee965363-5107-4c93-bf7d-fdf8d16987c1'	System	30 Aug 2020 22:00:36
User entered 'No (N)'	System	30 Aug 2020 22:00:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ee965363-5107-4c93-bf7d-fdf8d16987c1'	System	30 Aug 2020 22:00:36
User entered '30 Aug 2020 17:00'	System	30 Aug 2020 22:00:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 7'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:13:14', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '647d3dd5-a81b-44ff-84b9-f43382b9988b' User entered 'Yes (Y)'	System	31 Aug 2020 22:13:36
	System	31 Aug 2020 22:13:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:13:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '647d3dd5-a81b-44ff-84b9-f43382b9988b' User entered '97.7'	System	31 Aug 2020 22:13:36
	System	31 Aug 2020 22:13:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:13:30', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '647d3dd5-a81b-44ff-84b9-f43382b9988b'	System	31 Aug 2020 22:13:36
User entered 'No (N)'	System	31 Aug 2020 22:13:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:13:33', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '647d3dd5-a81b-44ff-84b9-f43382b9988b'	System	31 Aug 2020 22:13:36
User entered '31 Aug 2020 17:13'	System	31 Aug 2020 22:13:36

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:33', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '89fa3e86-735e-4336-adee-c486a21ec287'	System	25 Aug 2020 15:18:17
User entered 'None (1)'	System	25 Aug 2020 15:18:17

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:39', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '89fa3e86-735e-4336-adee-c486a21ec287'	System	25 Aug 2020 15:18:17
User entered 'No (N)'	System	25 Aug 2020 15:18:17

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '89fa3e86-735e-4336-adee-c486a21ec287'	System	25 Aug 2020 15:18:17
User entered 'No (N)'	System	25 Aug 2020 15:18:17

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '89fa3e86-735e-4336-adee-c486a21ec287'	System	25 Aug 2020 15:18:17
User entered 'None (1)'	System	25 Aug 2020 15:18:17

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:17:59', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '89fa3e86-735e-4336-adee-c486a21ec287'	System	25 Aug 2020 15:18:17
User entered '25 Aug 2020 10:17'	System	25 Aug 2020 15:18:17

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 09:55'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 12:25'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:28', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '8e573adb-f4e1-45c1-83af-2d0106bc5305'	System	25 Aug 2020 22:25:55
User entered 'None (1)'	System	25 Aug 2020 22:25:55

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:33', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '8e573adb-f4e1-45c1-83af-2d0106bc5305'	System	25 Aug 2020 22:25:55
User entered 'No (N)'	System	25 Aug 2020 22:25:55

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:37', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '8e573adb-f4e1-45c1-83af-2d0106bc5305'	System	25 Aug 2020 22:25:55
User entered 'No (N)'	System	25 Aug 2020 22:25:55

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:42', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '8e573adb-f4e1-45c1-83af-2d0106bc5305' User entered 'None (1)'	System	25 Aug 2020 22:25:55
	System	25 Aug 2020 22:25:55

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:25:52', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '8e573adb-f4e1-45c1-83af-2d0106bc5305' User entered '25 Aug 2020 17:25'	System	25 Aug 2020 22:25:55
	System	25 Aug 2020 22:25:55

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 13:20'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 2'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:07:59', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0caa2e4f-e57b-4945-b64b-29b48aa446b2'	System	26 Aug 2020 22:08:15
User entered 'None (1)'	System	26 Aug 2020 22:08:15

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:03', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0caa2e4f-e57b-4945-b64b-29b48aa446b2' User entered 'No (N)'	System	26 Aug 2020 22:08:15
	System	26 Aug 2020 22:08:15

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:07', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0caa2e4f-e57b-4945-b64b-29b48aa446b2' User entered 'No (N)'	System	26 Aug 2020 22:08:15
	System	26 Aug 2020 22:08:15

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0caa2e4f-e57b-4945-b64b-29b48aa446b2' User entered 'None (1)'	System	26 Aug 2020 22:08:15
	System	26 Aug 2020 22:08:15

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:13', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0caa2e4f-e57b-4945-b64b-29b48aa446b2' User entered '26 Aug 2020 17:08'	System	26 Aug 2020 22:08:15
	System	26 Aug 2020 22:08:15

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 3'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:41', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6cec2728-1f5c-4e24-b541-267a4c092d53'	System	27 Aug 2020 22:05:59
User entered 'None (1)'	System	27 Aug 2020 22:05:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:47', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6cec2728-1f5c-4e24-b541-267a4c092d53'	System	27 Aug 2020 22:05:59
User entered 'No (N)'	System	27 Aug 2020 22:05:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6cec2728-1f5c-4e24-b541-267a4c092d53'	System	27 Aug 2020 22:05:59
User entered 'No (N)'	System	27 Aug 2020 22:05:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:54', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6cec2728-1f5c-4e24-b541-267a4c092d53'	System	27 Aug 2020 22:05:59
User entered 'None (1)'	System	27 Aug 2020 22:05:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:05:57', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6cec2728-1f5c-4e24-b541-267a4c092d53' User entered '27 Aug 2020 17:05'	System	27 Aug 2020 22:05:59
	System	27 Aug 2020 22:05:59

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 4'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:34', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5dbbc2b3-eca5-4111-839a-e4286e94c70d' User entered 'None (1)'	System	28 Aug 2020 22:07:54
	System	28 Aug 2020 22:07:54

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:39', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5dbbc2b3-eca5-4111-839a-e4286e94c70d' User entered 'No (N)'	System	28 Aug 2020 22:07:54
	System	28 Aug 2020 22:07:54

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:44', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5dbbc2b3-eca5-4111-839a-e4286e94c70d' User entered 'No (N)'	System	28 Aug 2020 22:07:54
	System	28 Aug 2020 22:07:54

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:48', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5dbbc2b3-eca5-4111-839a-e4286e94c70d' User entered 'None (1)'	System	28 Aug 2020 22:07:54
	System	28 Aug 2020 22:07:54

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5dbbc2b3-eca5-4111-839a-e4286e94c70d' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 22:07:54
	System	28 Aug 2020 22:07:54

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 5'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:38', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6fe88390-2db5-4ff7-9ae0-421ef8982837'	System	29 Aug 2020 22:02:53
User entered 'None (1)'	System	29 Aug 2020 22:02:53

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6fe88390-2db5-4ff7-9ae0-421ef8982837'	System	29 Aug 2020 22:02:53
User entered 'No (N)'	System	29 Aug 2020 22:02:53

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:46', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6fe88390-2db5-4ff7-9ae0-421ef8982837'	System	29 Aug 2020 22:02:53
User entered 'No (N)'	System	29 Aug 2020 22:02:53

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:48', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6fe88390-2db5-4ff7-9ae0-421ef8982837'	System	29 Aug 2020 22:02:53
User entered 'None (1)'	System	29 Aug 2020 22:02:53

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6fe88390-2db5-4ff7-9ae0-421ef8982837'	System	29 Aug 2020 22:02:53
User entered '29 Aug 2020 17:02'	System	29 Aug 2020 22:02:53

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 6'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:34', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '02c50ac5-4164-4736-b019-ebac22a3df05'	System	30 Aug 2020 22:00:49
User entered 'None (1)'	System	30 Aug 2020 22:00:49

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:38', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '02c50ac5-4164-4736-b019-ebac22a3df05' User entered 'No (N)'	System	30 Aug 2020 22:00:49
	System	30 Aug 2020 22:00:49

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:42', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '02c50ac5-4164-4736-b019-ebac22a3df05' User entered 'No (N)'	System	30 Aug 2020 22:00:49
	System	30 Aug 2020 22:00:49

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '02c50ac5-4164-4736-b019-ebac22a3df05' User entered 'None (1)'	System	30 Aug 2020 22:00:49
	System	30 Aug 2020 22:00:49

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:47', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '02c50ac5-4164-4736-b019-ebac22a3df05'	System	30 Aug 2020 22:00:49
User entered '30 Aug 2020 17:00'	System	30 Aug 2020 22:00:49

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 7'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:13:52', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fa7912c9-182c-4315-857f-d51d86e666b7'	System	31 Aug 2020 22:14:26
User entered 'None (1)'	System	31 Aug 2020 22:14:26

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:02', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fa7912c9-182c-4315-857f-d51d86e666b7'	System	31 Aug 2020 22:14:26
User entered 'No (N)'	System	31 Aug 2020 22:14:26

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fa7912c9-182c-4315-857f-d51d86e666b7'	System	31 Aug 2020 22:14:26
User entered 'No (N)'	System	31 Aug 2020 22:14:26

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:17', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fa7912c9-182c-4315-857f-d51d86e666b7'	System	31 Aug 2020 22:14:26
User entered 'None (1)'	System	31 Aug 2020 22:14:26

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fa7912c9-182c-4315-857f-d51d86e666b7' User entered '31 Aug 2020 17:14'	System	31 Aug 2020 22:14:26
	System	31 Aug 2020 22:14:26

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:07', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered 'None (0)'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered 'None (0)'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:13', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered 'None (0)'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:17', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered 'None (0)'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:20', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered 'None (0)'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered 'None (0)'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered 'No (N)'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T10:18:37', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'be17a147-a294-4545-a7cb-669d93c14bab' User entered '25 Aug 2020 10:18'	System	25 Aug 2020 15:18:38
	System	25 Aug 2020 15:18:38

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 09:55'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 12:25'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df' User entered 'None (0)'	System	25 Aug 2020 22:26:41
	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:03', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df' User entered 'None (0)'	System	25 Aug 2020 22:26:41
	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:15', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df' User entered 'None (0)'	System	25 Aug 2020 22:26:41
	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:24', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df' User entered 'None (0)'	System	25 Aug 2020 22:26:41
	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:28', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df' User entered 'None (0)'	System	25 Aug 2020 22:26:41
	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:31', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df' User entered 'None (0)'	System	25 Aug 2020 22:26:41
	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:36', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df'	System	25 Aug 2020 22:26:41
User entered 'No (N)'	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-25T17:26:40', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1764ab67-bcec-4383-a067-aeb635c912df' User entered '25 Aug 2020 17:26'	System	25 Aug 2020 22:26:41
	System	25 Aug 2020 22:26:41

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Aug 2020 13:20'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 2'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:20', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136'	System	26 Aug 2020 22:08:47
User entered 'None (0)'	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136' User entered 'None (0)'	System	26 Aug 2020 22:08:47
	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:27', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136' User entered 'None (0)'	System	26 Aug 2020 22:08:47
	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:31', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136' User entered 'None (0)'	System	26 Aug 2020 22:08:47
	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:35', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136' User entered 'None (0)'	System	26 Aug 2020 22:08:47
	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:37', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136' User entered 'None (0)'	System	26 Aug 2020 22:08:47
	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136'	System	26 Aug 2020 22:08:47
User entered 'No (N)'	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-26T17:08:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'b7c9f555-e8f1-4df2-af62-2131d098d136'	System	26 Aug 2020 22:08:47
User entered '26 Aug 2020 17:08'	System	26 Aug 2020 22:08:47

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 3'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:12', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered 'None (0)'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:15', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered 'None (0)'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:19', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered 'None (0)'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:28', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered 'None (0)'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:35', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered 'None (0)'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:38', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered 'None (0)'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:41', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered 'No (N)'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-27T17:06:44', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '002f2201-d539-45a8-ba2f-196a3684ddec' User entered '27 Aug 2020 17:06'	System	27 Aug 2020 22:06:48
	System	27 Aug 2020 22:06:48

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 4'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:07:57', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87'	System	28 Aug 2020 22:08:19
User entered 'None (0)'	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:08:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87'	System	28 Aug 2020 22:08:19
User entered 'None (0)'	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:08:03', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87' User entered 'None (0)'	System	28 Aug 2020 22:08:19
	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:08:06', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87' User entered 'None (0)'	System	28 Aug 2020 22:08:19
	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:08:08', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87'	System	28 Aug 2020 22:08:19
User entered 'None (0)'	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:08:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87'	System	28 Aug 2020 22:08:19
User entered 'None (0)'	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:08:13', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87'	System	28 Aug 2020 22:08:19
User entered 'No (N)'	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-28T17:08:16', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cf26b4c1-8f73-47cc-879d-a26df9af0d87'	System	28 Aug 2020 22:08:19
User entered '28 Aug 2020 17:08'	System	28 Aug 2020 22:08:19

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 5'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:02:56', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered 'None (0)'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:03:02', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered 'None (0)'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:03:06', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered 'None (0)'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:03:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered 'None (0)'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:03:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered 'None (0)'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:03:14', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered 'None (0)'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:03:18', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered 'No (N)'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-29T17:03:20', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd91c082a-f88d-4f0e-a107-50bb68dd72bb' User entered '29 Aug 2020 17:03'	System	29 Aug 2020 22:03:22
	System	29 Aug 2020 22:03:22

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 6'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:54', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa' User entered 'None (0)'	System	30 Aug 2020 22:01:13
	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:56', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa' User entered 'None (0)'	System	30 Aug 2020 22:01:13
	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:00:59', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa' User entered 'None (0)'	System	30 Aug 2020 22:01:13
	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:01:01', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa' User entered 'None (0)'	System	30 Aug 2020 22:01:13
	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:01:04', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa' User entered 'None (0)'	System	30 Aug 2020 22:01:13
	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:01:06', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa' User entered 'None (0)'	System	30 Aug 2020 22:01:13
	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:01:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa'	System	30 Aug 2020 22:01:13
User entered 'No (N)'	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-30T17:01:12', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'e0acb8ce-c56a-49a8-bd7a-d769de38d2fa' User entered '30 Aug 2020 17:01'	System	30 Aug 2020 22:01:13
	System	30 Aug 2020 22:01:13

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 7'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:34', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered 'None (0)'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:41', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered 'None (0)'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:47', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered 'None (0)'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered 'None (0)'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:54', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered 'None (0)'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:14:57', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered 'None (0)'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:15:05', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered 'No (N)'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-08-31T17:15:08', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '29b457c9-4f74-47a2-b063-0ca28d13172e' User entered '31 Aug 2020 17:15'	System	31 Aug 2020 22:15:10
	System	31 Aug 2020 22:15:10

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:40:40

US3442074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:54:41
User entered 'Yes (Y)'		02 Sep 2020 16:56:57

US3442074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:54:44
User entered '2 Sep 2020'		02 Sep 2020 16:56:57

US3442074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:54:47
User entered 'Contact Made (CONTACT MADE)'		02 Sep 2020 16:56:57

US3442074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:44:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:54:49
User entered empty.		02 Sep 2020 16:56:57

US3442074

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:54:53
User entered 'Yes (Y)'		02 Sep 2020 16:57:02

US3442074

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User entered '1'	System	02 Sep 2020 16:57:02

US3442074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:56:27
User entered 'Yes (Y)'		09 Sep 2020 17:49:34

US3442074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:56:29
User entered '9 Sep 2020'		09 Sep 2020 17:49:34

US3442074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:56:34
User entered 'Contact Made (CONTACT MADE)'		09 Sep 2020 17:49:34

US3442074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:56:37
User entered empty.		09 Sep 2020 17:49:34

US3442074

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:56:41
User entered 'Yes (Y)'		09 Sep 2020 17:50:02

US3442074

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User entered '1'	System	09 Sep 2020 17:50:02

US3442074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:33:42
User entered 'Yes (Y)'		16 Sep 2020 18:18:23

US3442074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:33:42
User entered '16 Sep 2020'		16 Sep 2020 18:18:23

US3442074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:33:42
User entered 'Contact Made (CONTACT MADE)'		16 Sep 2020 18:18:23

US3442074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:33:42
User entered empty.		16 Sep 2020 18:18:23

US3442074

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:33:46
User entered 'Yes (Y)'		16 Sep 2020 18:18:29

US3442074

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:43:19
User entered '1'	System	16 Sep 2020 18:18:29

US3442074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:34:23
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:01:59

US3442074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:34:23
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:01:59

US3442074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:34:23
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:01:59

US3442074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'VISIT2'	System	22 Sep 2020 14:01:59

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User accepted default value 'Pre-Dose (PREDOSE)'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered 'Yes (Y)'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '22 Sep 2020'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '08:23'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '22 Sep 2020 08:23'	System	22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '97.0' F		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered 'Oral (Oral)'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered empty.		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '99'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'bpm'	System	22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '14'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'breaths/min'	System	22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '158'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'mmHg'	System	22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '83'		22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'mmHg'	System	22 Sep 2020 22:20:38

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User accepted default value 'Post-Dose (POSTDOSE)'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered 'Yes (Y)'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '22 Sep 2020'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '09:59'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '22 Sep 2020 09:59'	System	22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '97.9' F		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered 'Oral (Oral)'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered empty.		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '96'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'bpm'	System	22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '14'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'breaths/min'	System	22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '147'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'mmHg'	System	22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:12
User entered '86'		22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'mmHg'	System	22 Sep 2020 22:23:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:28
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:02:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:28
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:02:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:36:46
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:36:46
User entered empty.	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 21:36:46
User entered empty.	Melody Dufrene (b) (4)	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:36:46
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:36:46
User entered '09:24'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '22 Sep 2020 09:24'	System	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:36:46
User entered 'Left Arm (LEFT ARM)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
DataPoint Verified.		22 Dec 2020 21:36:46
User entered 'ONCE'	System	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 14:28:09

US3442074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:42
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:14

US3442074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:42
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:14

US3442074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:42
User entered '08:40'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:14

US3442074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '22 Sep 2020 08:40'	System	22 Sep 2020 14:03:14

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:48
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:48
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:48
User entered '08:43'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '22 Sep 2020 08:43'	System	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:48
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:48
User entered empty.	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered empty.	System	22 Sep 2020 14:03:31

US3442074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:35:52
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:03:36

US3442074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '1'	System	22 Sep 2020 14:03:36

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:58:30', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '06eb91c4-11d9-4b1c-b8bc-1ce0362982f8' User entered 'Yes (Y)'	System	22 Sep 2020 14:58:55
	System	22 Sep 2020 14:58:55

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:58:41', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '06eb91c4-11d9-4b1c-b8bc-1ce0362982f8' User entered '97.9'	System	22 Sep 2020 14:58:55
	System	22 Sep 2020 14:58:55

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:58:46', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '06eb91c4-11d9-4b1c-b8bc-1ce0362982f8'	System	22 Sep 2020 14:58:55
User entered 'No (N)'	System	22 Sep 2020 14:58:55

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:58:53', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '06eb91c4-11d9-4b1c-b8bc-1ce0362982f8' User entered '22 Sep 2020 09:58'	System	22 Sep 2020 14:58:55
	System	22 Sep 2020 14:58:55

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 09:44'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 12:14'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:11:12', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '41039e1c-c063-4af3-a751-fab2613f0bdb' User entered 'Yes (Y)'	System	22 Sep 2020 23:11:37
	System	22 Sep 2020 23:11:37

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:11:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '41039e1c-c063-4af3-a751-fab2613f0bdb' User entered '97.7'	System	22 Sep 2020 23:11:37
	System	22 Sep 2020 23:11:37

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:11:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '41039e1c-c063-4af3-a751-fab2613f0bdb' User entered 'No (N)'	System	22 Sep 2020 23:11:37
	System	22 Sep 2020 23:11:37

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:11:35', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '41039e1c-c063-4af3-a751-fab2613f0bdb' User entered '22 Sep 2020 18:11'	System	22 Sep 2020 23:11:37
	System	22 Sep 2020 23:11:37

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 13:09'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 2'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:09:30', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd6726350-5adf-49b2-97fa-f37d4cbbb408' User entered 'Yes (Y)'	System	23 Sep 2020 22:09:54
	System	23 Sep 2020 22:09:54

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:09:39', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd6726350-5adf-49b2-97fa-f37d4cbbb408' User entered '97.8'	System	23 Sep 2020 22:09:54
	System	23 Sep 2020 22:09:54

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:09:44', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd6726350-5adf-49b2-97fa-f37d4cbbb408'	System	23 Sep 2020 22:09:54
User entered 'No (N)'	System	23 Sep 2020 22:09:54

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:09:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd6726350-5adf-49b2-97fa-f37d4cbbb408'	System	23 Sep 2020 22:09:54
User entered '23 Sep 2020 17:09'	System	23 Sep 2020 22:09:54

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 3'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:42:31', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ba647d8b-e423-4455-a64f-ffff3e4be9a'	System	25 Sep 2020 00:42:48
User entered 'Yes (Y)'	System	25 Sep 2020 00:42:48

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:42:37', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ba647d8b-e423-4455-a64f-ffff3e4be9a' User entered '97.8'	System	25 Sep 2020 00:42:48
	System	25 Sep 2020 00:42:48

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:42:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ba647d8b-e423-4455-a64f-ffff3e4be9a'	System	25 Sep 2020 00:42:48
User entered 'No (N)'	System	25 Sep 2020 00:42:48

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:42:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ba647d8b-e423-4455-a64f-ffff3e4be9a'	System	25 Sep 2020 00:42:48
User entered '24 Sep 2020 19:42'	System	25 Sep 2020 00:42:48

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 4'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:17:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fef53951-abab-40b0-9bcb-d14fc82f0193' User entered 'Yes (Y)'	System	25 Sep 2020 23:17:58
	System	25 Sep 2020 23:17:58

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:17:48', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fef53951-abab-40b0-9bcb-d14fc82f0193' User entered '97.8'	System	25 Sep 2020 23:17:58
	System	25 Sep 2020 23:17:58

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:17:53', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fef53951-abab-40b0-9bcb-d14fc82f0193'	System	25 Sep 2020 23:17:58
User entered 'No (N)'	System	25 Sep 2020 23:17:58

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:17:56', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'fef53951-abab-40b0-9bcb-d14fc82f0193'	System	25 Sep 2020 23:17:58
User entered '25 Sep 2020 18:17'	System	25 Sep 2020 23:17:58

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 5'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:21:58', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ba88890-fdf6-4690-8867-d3c675c0a33f' User entered 'Yes (Y)'	System	26 Sep 2020 22:22:14
	System	26 Sep 2020 22:22:14

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:05', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ba88890-fdf6-4690-8867-d3c675c0a33f' User entered '97.8'	System	26 Sep 2020 22:22:14
	System	26 Sep 2020 22:22:14

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ba88890-fdf6-4690-8867-d3c675c0a33f' User entered 'No (N)'	System	26 Sep 2020 22:22:14
	System	26 Sep 2020 22:22:14

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:12', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6ba88890-fdf6-4690-8867-d3c675c0a33f' User entered '26 Sep 2020 17:22'	System	26 Sep 2020 22:22:14
	System	26 Sep 2020 22:22:14

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 6'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:04', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7a6ac85b-e67a-40e9-a506-da43bf6742e2' User entered 'Yes (Y)'	System	27 Sep 2020 23:14:20
	System	27 Sep 2020 23:14:20

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7a6ac85b-e67a-40e9-a506-da43bf6742e2' User entered '97.8'	System	27 Sep 2020 23:14:20
	System	27 Sep 2020 23:14:20

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:12', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7a6ac85b-e67a-40e9-a506-da43bf6742e2' User entered 'No (N)'	System	27 Sep 2020 23:14:20
	System	27 Sep 2020 23:14:20

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:15', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '7a6ac85b-e67a-40e9-a506-da43bf6742e2'	System	27 Sep 2020 23:14:20
User entered '27 Sep 2020 18:14'	System	27 Sep 2020 23:14:20

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 7'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:01', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f43de3aa-103f-4ba7-9b38-f4dd8a597d3a' User entered 'Yes (Y)'	System	28 Sep 2020 22:15:26
	System	28 Sep 2020 22:15:26

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f43de3aa-103f-4ba7-9b38-f4dd8a597d3a' User entered '97.8'	System	28 Sep 2020 22:15:26
	System	28 Sep 2020 22:15:26

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:18', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f43de3aa-103f-4ba7-9b38-f4dd8a597d3a' User entered 'No (N)'	System	28 Sep 2020 22:15:26
	System	28 Sep 2020 22:15:26

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'f43de3aa-103f-4ba7-9b38-f4dd8a597d3a' User entered '28 Sep 2020 17:15'	System	28 Sep 2020 22:15:26
	System	28 Sep 2020 22:15:26

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:02', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2f66bc2d-97ec-42ed-a53e-a9699a10576c' User entered 'None (1)'	System	22 Sep 2020 14:59:44
	System	22 Sep 2020 14:59:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:06', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2f66bc2d-97ec-42ed-a53e-a9699a10576c' User entered 'No (N)'	System	22 Sep 2020 14:59:44
	System	22 Sep 2020 14:59:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:09', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2f66bc2d-97ec-42ed-a53e-a9699a10576c' User entered 'No (N)'	System	22 Sep 2020 14:59:44
	System	22 Sep 2020 14:59:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:36', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2f66bc2d-97ec-42ed-a53e-a9699a10576c' User entered 'None (1)'	System	22 Sep 2020 14:59:44
	System	22 Sep 2020 14:59:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:40', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2f66bc2d-97ec-42ed-a53e-a9699a10576c' User entered '22 Sep 2020 09:59'	System	22 Sep 2020 14:59:44
	System	22 Sep 2020 14:59:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 09:44'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 12:14'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:11:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1aae7dbd-5f6f-45fb-8e47-2b1a72c622c0'	System	22 Sep 2020 23:12:09
User entered 'None (1)'	System	22 Sep 2020 23:12:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:11:50', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1aae7dbd-5f6f-45fb-8e47-2b1a72c622c0' User entered 'No (N)'	System	22 Sep 2020 23:12:09
	System	22 Sep 2020 23:12:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:11:55', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1aae7dbd-5f6f-45fb-8e47-2b1a72c622c0' User entered 'No (N)'	System	22 Sep 2020 23:12:09
	System	22 Sep 2020 23:12:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:02', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1aae7dbd-5f6f-45fb-8e47-2b1a72c622c0'	System	22 Sep 2020 23:12:09
User entered 'None (1)'	System	22 Sep 2020 23:12:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:06', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1aae7dbd-5f6f-45fb-8e47-2b1a72c622c0' User entered '22 Sep 2020 18:12'	System	22 Sep 2020 23:12:09
	System	22 Sep 2020 23:12:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 13:09'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 2'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:09:57', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '61dee475-50e0-410d-925e-1610a550bdd8'	System	23 Sep 2020 22:10:14
User entered 'None (1)'	System	23 Sep 2020 22:10:14

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '61dee475-50e0-410d-925e-1610a550bdd8' User entered 'No (N)'	System	23 Sep 2020 22:10:14
	System	23 Sep 2020 22:10:14

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:04', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '61dee475-50e0-410d-925e-1610a550bdd8' User entered 'No (N)'	System	23 Sep 2020 22:10:14
	System	23 Sep 2020 22:10:14

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:08', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '61dee475-50e0-410d-925e-1610a550bdd8'	System	23 Sep 2020 22:10:14
User entered 'None (1)'	System	23 Sep 2020 22:10:14

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '61dee475-50e0-410d-925e-1610a550bdd8'	System	23 Sep 2020 22:10:14
User entered '23 Sep 2020 17:10'	System	23 Sep 2020 22:10:14

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 3'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:42:50', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cbfeb7a9-2c98-48ee-b2ab-483280063b9a' User entered 'None (1)'	System	25 Sep 2020 00:43:11
	System	25 Sep 2020 00:43:11

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:42:53', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cbfeb7a9-2c98-48ee-b2ab-483280063b9a' User entered 'No (N)'	System	25 Sep 2020 00:43:11
	System	25 Sep 2020 00:43:11

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:42:56', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cbfeb7a9-2c98-48ee-b2ab-483280063b9a' User entered 'No (N)'	System	25 Sep 2020 00:43:11
	System	25 Sep 2020 00:43:11

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:04', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cbfeb7a9-2c98-48ee-b2ab-483280063b9a' User entered 'None (1)'	System	25 Sep 2020 00:43:11
	System	25 Sep 2020 00:43:11

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:08', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'cbfeb7a9-2c98-48ee-b2ab-483280063b9a'	System	25 Sep 2020 00:43:11
User entered '24 Sep 2020 19:43'	System	25 Sep 2020 00:43:11

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 4'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:01', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3d2019a5-5233-46b6-a22f-8e29262bd401' User entered 'None (1)'	System	25 Sep 2020 23:18:15
	System	25 Sep 2020 23:18:15

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:05', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3d2019a5-5233-46b6-a22f-8e29262bd401' User entered 'No (N)'	System	25 Sep 2020 23:18:15
	System	25 Sep 2020 23:18:15

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:08', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3d2019a5-5233-46b6-a22f-8e29262bd401' User entered 'No (N)'	System	25 Sep 2020 23:18:15
	System	25 Sep 2020 23:18:15

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:10', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3d2019a5-5233-46b6-a22f-8e29262bd401' User entered 'None (1)'	System	25 Sep 2020 23:18:15
	System	25 Sep 2020 23:18:15

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:13', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3d2019a5-5233-46b6-a22f-8e29262bd401' User entered '25 Sep 2020 18:18'	System	25 Sep 2020 23:18:15
	System	25 Sep 2020 23:18:15

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 5'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:18', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '556ddb86-7934-4104-b1e2-dcd4223e92cd'	System	26 Sep 2020 22:22:35
User entered 'None (1)'	System	26 Sep 2020 22:22:35

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:22', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '556ddb86-7934-4104-b1e2-dcd4223e92cd' User entered 'No (N)'	System	26 Sep 2020 22:22:35
	System	26 Sep 2020 22:22:35

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:25', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '556ddb86-7934-4104-b1e2-dcd4223e92cd' User entered 'No (N)'	System	26 Sep 2020 22:22:35
	System	26 Sep 2020 22:22:35

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '556ddb86-7934-4104-b1e2-dcd4223e92cd' User entered 'None (1)'	System	26 Sep 2020 22:22:35
	System	26 Sep 2020 22:22:35

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:32', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '556ddb86-7934-4104-b1e2-dcd4223e92cd' User entered '26 Sep 2020 17:22'	System	26 Sep 2020 22:22:35
	System	26 Sep 2020 22:22:35

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 6'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:20', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0b7059db-17fb-48ae-b441-698767a12eb3' User entered 'None (1)'	System	27 Sep 2020 23:14:36
	System	27 Sep 2020 23:14:36

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0b7059db-17fb-48ae-b441-698767a12eb3' User entered 'No (N)'	System	27 Sep 2020 23:14:36
	System	27 Sep 2020 23:14:36

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:25', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0b7059db-17fb-48ae-b441-698767a12eb3' User entered 'No (N)'	System	27 Sep 2020 23:14:36
	System	27 Sep 2020 23:14:36

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0b7059db-17fb-48ae-b441-698767a12eb3' User entered 'None (1)'	System	27 Sep 2020 23:14:36
	System	27 Sep 2020 23:14:36

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:31', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0b7059db-17fb-48ae-b441-698767a12eb3' User entered '27 Sep 2020 18:14'	System	27 Sep 2020 23:14:36
	System	27 Sep 2020 23:14:36

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 7'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5772bb99-df60-4383-a850-9e328afb9517'	System	28 Sep 2020 22:15:44
User entered 'None (1)'	System	28 Sep 2020 22:15:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:32', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5772bb99-df60-4383-a850-9e328afb9517'	System	28 Sep 2020 22:15:44
User entered 'No (N)'	System	28 Sep 2020 22:15:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:34', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5772bb99-df60-4383-a850-9e328afb9517'	System	28 Sep 2020 22:15:44
User entered 'No (N)'	System	28 Sep 2020 22:15:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:37', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5772bb99-df60-4383-a850-9e328afb9517'	System	28 Sep 2020 22:15:44
User entered 'None (1)'	System	28 Sep 2020 22:15:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:40', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '5772bb99-df60-4383-a850-9e328afb9517' User entered '28 Sep 2020 17:15'	System	28 Sep 2020 22:15:44
	System	28 Sep 2020 22:15:44

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered 'None (0)'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:48', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered 'None (0)'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered 'None (0)'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:54', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered 'None (0)'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:56', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered 'None (0)'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T09:59:59', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered 'None (0)'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T10:00:02', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered 'No (N)'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T10:00:06', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '1ba5720e-93f8-4fac-a22d-5dfea8242b2e' User entered '22 Sep 2020 10:00'	System	22 Sep 2020 15:00:19
	System	22 Sep 2020 15:00:19

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 09:44'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 12:14'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:15', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered 'None (0)'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:19', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered 'None (0)'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:24', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered 'None (0)'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:30', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered 'None (0)'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:35', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered 'None (0)'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:39', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered 'None (0)'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered 'No (N)'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-22T18:12:49', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'a97b01f2-101b-480c-ae95-8df42da6e7a6' User entered '22 Sep 2020 18:12'	System	22 Sep 2020 23:12:53
	System	22 Sep 2020 23:12:53

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '22 Sep 2020 13:09'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 2'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:17', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981' User entered 'None (0)'	System	23 Sep 2020 22:10:47
	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:20', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981' User entered 'None (0)'	System	23 Sep 2020 22:10:47
	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:24', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981' User entered 'None (0)'	System	23 Sep 2020 22:10:47
	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:27', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981' User entered 'None (0)'	System	23 Sep 2020 22:10:47
	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:30', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981' User entered 'None (0)'	System	23 Sep 2020 22:10:47
	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:33', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981' User entered 'None (0)'	System	23 Sep 2020 22:10:47
	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:38', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981'	System	23 Sep 2020 22:10:47
User entered 'No (N)'	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-23T17:10:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '437fe241-62e0-4df9-b1e0-013923608981' User entered '23 Sep 2020 17:10'	System	23 Sep 2020 22:10:47
	System	23 Sep 2020 22:10:47

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 3'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:16', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered 'None (0)'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:21', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered 'None (0)'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:24', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered 'None (0)'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:27', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered 'None (0)'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered 'None (0)'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:32', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered 'None (0)'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:37', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered 'No (N)'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-24T19:43:40', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db458e11-5fba-4f1d-8b64-cbe1c6f543be' User entered '24 Sep 2020 19:43'	System	25 Sep 2020 00:43:44
	System	25 Sep 2020 00:43:44

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 4'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:18', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered 'None (0)'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:20', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered 'None (0)'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:22', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered 'None (0)'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:24', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered 'None (0)'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:27', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered 'None (0)'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered 'None (0)'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:31', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered 'No (N)'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-25T18:18:33', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63852f66-aec0-4641-8257-0d7a2c68ab25' User entered '25 Sep 2020 18:18'	System	25 Sep 2020 23:18:37
	System	25 Sep 2020 23:18:37

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 5'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:39', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered 'None (0)'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered 'None (0)'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered 'None (0)'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:48', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered 'None (0)'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:52', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered 'None (0)'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:55', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered 'None (0)'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:22:58', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered 'No (N)'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-26T17:23:01', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63b630a8-6a6e-4b6c-b168-177b822cdf19' User entered '26 Sep 2020 17:23'	System	26 Sep 2020 22:23:04
	System	26 Sep 2020 22:23:04

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 6'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:37', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17'	System	27 Sep 2020 23:14:57
User entered 'None (0)'	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:39', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17' User entered 'None (0)'	System	27 Sep 2020 23:14:57
	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:41', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17' User entered 'None (0)'	System	27 Sep 2020 23:14:57
	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:44', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17' User entered 'None (0)'	System	27 Sep 2020 23:14:57
	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:46', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17' User entered 'None (0)'	System	27 Sep 2020 23:14:57
	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:49', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17' User entered 'None (0)'	System	27 Sep 2020 23:14:57
	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17'	System	27 Sep 2020 23:14:57
User entered 'No (N)'	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-27T18:14:54', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '6d2d638e-f8d2-41af-9f8a-4a196cf7cb17' User entered '27 Sep 2020 18:14'	System	27 Sep 2020 23:14:57
	System	27 Sep 2020 23:14:57

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
Data entry locked.	System	22 Sep 2020 14:28:09
User entered 'Day 7'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:45', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711' User entered 'None (0)'	System	28 Sep 2020 22:16:05
	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:47', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711' User entered 'None (0)'	System	28 Sep 2020 22:16:05
	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:49', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711' User entered 'None (0)'	System	28 Sep 2020 22:16:05
	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:53', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711' User entered 'None (0)'	System	28 Sep 2020 22:16:05
	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:55', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711' User entered 'None (0)'	System	28 Sep 2020 22:16:05
	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:15:58', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711' User entered 'None (0)'	System	28 Sep 2020 22:16:05
	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

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 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:16:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711'	System	28 Sep 2020 22:16:05
User entered 'No (N)'	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-09-28T17:16:03', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '93fb7f4a-d7cb-42c2-ba04-b63d462be711' User entered '28 Sep 2020 17:16'	System	28 Sep 2020 22:16:05
	System	28 Sep 2020 22:16:05

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:28:09

US3442074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:28:09

US3442074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:14
User entered 'Yes (Y)'		29 Sep 2020 19:11:26

US3442074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	22 Dec 2020 21:39:14
User entered '29 Sep 2020'		29 Sep 2020 19:11:26

US3442074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:14
User entered 'Contact Made (CONTACT MADE)'		29 Sep 2020 19:11:26

US3442074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:14
User entered empty.		29 Sep 2020 19:11:26

US3442074

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:34
User entered 'Yes (Y)'		29 Sep 2020 19:11:52

US3442074

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '1'	System	29 Sep 2020 19:11:52

US3442074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:40:01
User entered 'Yes (Y)'		07 Oct 2020 21:01:31

US3442074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:40:01
User entered '6 Oct 2020'		07 Oct 2020 21:01:31

US3442074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4)	22 Dec 2020 21:40:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 21:01:31

US3442074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:40:01
User entered empty.		07 Oct 2020 21:01:31

US3442074

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:40:04
User entered 'Yes (Y)'		07 Oct 2020 21:01:37

US3442074

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '1'	System	07 Oct 2020 21:01:37

US3442074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:41:46
User entered 'Yes (Y)'		23 Oct 2020 14:53:16

US3442074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:41:46
User entered '13 Oct 2020'		23 Oct 2020 14:53:16

US3442074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:41:46
User entered 'Contact Made (CONTACT MADE)'		23 Oct 2020 14:53:16

US3442074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:41:46
User entered empty.		23 Oct 2020 14:53:16

US3442074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:09
User entered 'Yes (Y)'		23 Oct 2020 14:53:22

US3442074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '1'	System	23 Oct 2020 14:53:22

US3442074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:13
User entered 'Yes (Y)'		23 Oct 2020 14:53:44

US3442074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:13
User entered '23 Oct 2020'		23 Oct 2020 14:53:44

US3442074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:13
User entered 'Clinic (Clinic)'		23 Oct 2020 14:53:44

US3442074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User entered 'VISIT3'	System	23 Oct 2020 14:53:44

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered 'No (N)'		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User entered empty.	System	23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User entered empty.	System	23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User entered empty.	System	23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User entered empty.	System	23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:53
User entered empty.		23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User entered empty.	System	23 Oct 2020 14:53:50

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57

US3442074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57

US3442074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:56
User entered 'No (N)'		23 Oct 2020 14:53:56

US3442074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:42:56
User entered empty.		23 Oct 2020 14:53:56

US3442074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:43:11
User entered 'Yes (Y)'		23 Oct 2020 14:54:09

US3442074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:43:11
User entered '23 Oct 2020'		23 Oct 2020 14:54:09

US3442074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:43:11
User entered '08:32'		23 Oct 2020 14:54:09

US3442074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:57
User entered '23 Oct 2020 08:32'	System	23 Oct 2020 14:54:09

US3442074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:43:18
User entered 'Yes (Y)'		23 Oct 2020 14:54:14

US3442074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '1'	System	23 Oct 2020 14:54:14

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 64'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 71'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:41:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered 'Day 78'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
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US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
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Folder: Safety Follow Up Diary (1)

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

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US3442074

Folder: Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
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US3442074

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
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US3442074

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 14:40:40

US3442074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:31
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	07 Apr 2021 16:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:13:06
Data entry locked.	System	25 Aug 2020 14:40:40
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 14:40:40

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-07T17:58:50', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '25035fda-c069-45f7-90eb-e635da19b3bb' User entered 'No (N)'	System	07 Dec 2020 23:59:13
	System	07 Dec 2020 23:59:13

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-07T17:58:58', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '25035fda-c069-45f7-90eb-e635da19b3bb' User entered 'No (N)'	System	07 Dec 2020 23:59:13

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-07T17:59:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '25035fda-c069-45f7-90eb-e635da19b3bb' User entered '07 Dec 2020 17:59:11'	System	07 Dec 2020 23:59:13
	System	07 Dec 2020 23:59:13

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-14T12:01:13', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '73cf4d43-bcde-4ad5-9fe7-b611d0b8d256'	System	14 Dec 2020 18:01:41
User entered 'No (N)'	System	14 Dec 2020 18:01:41

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-14T12:01:24', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '73cf4d43-bcde-4ad5-9fe7-b611d0b8d256'	System	14 Dec 2020 18:01:41
User entered 'No (N)'	System	14 Dec 2020 18:01:41

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-14T12:01:38', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '73cf4d43-bcde-4ad5-9fe7-b611d0b8d256' User entered '14 Dec 2020 12:01:38'	System	14 Dec 2020 18:01:41
	System	14 Dec 2020 18:01:41

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-17T10:32:18', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'c841118b-b2ec-43d8-a2fe-87f684e43a34'	System	17 Dec 2020 16:32:32
User entered 'No (N)'	System	17 Dec 2020 16:32:32

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-17T10:32:23', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'c841118b-b2ec-43d8-a2fe-87f684e43a34'	System	17 Dec 2020 16:32:32
User entered 'No (N)'	System	17 Dec 2020 16:32:32

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-17T10:32:29', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'c841118b-b2ec-43d8-a2fe-87f684e43a34' User entered '17 Dec 2020 10:32:29'	System	17 Dec 2020 16:32:32
	System	17 Dec 2020 16:32:32

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-24T11:09:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '507a5b81-f633-4646-9b8d-0004a559c34d' User entered 'No (N)'	System	24 Dec 2020 17:09:26
	System	24 Dec 2020 17:09:26

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-24T11:09:20', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '507a5b81-f633-4646-9b8d-0004a559c34d' User entered 'No (N)'	System	24 Dec 2020 17:09:26
	System	24 Dec 2020 17:09:26

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2020-12-24T11:09:24', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '507a5b81-f633-4646-9b8d-0004a559c34d' User entered '24 Dec 2020 11:09:24'	System	24 Dec 2020 17:09:26
	System	24 Dec 2020 17:09:26

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-01T09:00:57', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '234288ef-dada-4861-87f1-1a6abd370997'	System	01 Jan 2021 15:01:11
User entered 'No (N)'	System	01 Jan 2021 15:01:11

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-01T09:01:04', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '234288ef-dada-4861-87f1-1a6abd370997'	System	01 Jan 2021 15:01:11
User entered 'No (N)'	System	01 Jan 2021 15:01:11

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-01T09:01:08', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '234288ef-dada-4861-87f1-1a6abd370997'	System	01 Jan 2021 15:01:11
User entered '01 Jan 2021 09:01:08'	System	01 Jan 2021 15:01:11

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-07T12:23:05', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2c2dbef5-1776-44ba-b554-9a9f9f7f46b5' User entered 'No (N)'	System	07 Jan 2021 18:23:19
	System	07 Jan 2021 18:23:19

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-07T12:23:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2c2dbef5-1776-44ba-b554-9a9f9f7f46b5'	System	07 Jan 2021 18:23:19
User entered 'No (N)'	System	07 Jan 2021 18:23:19

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-07T12:23:15', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '2c2dbef5-1776-44ba-b554-9a9f9f7f46b5' User entered '07 Jan 2021 12:23:15'	System	07 Jan 2021 18:23:19
	System	07 Jan 2021 18:23:19

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-14T14:57:51', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'c8c4d647-b91f-4fb2-85be-7512ea0177cb'	System	14 Jan 2021 20:58:03
User entered 'No (N)'	System	14 Jan 2021 20:58:03

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-14T14:57:57', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'c8c4d647-b91f-4fb2-85be-7512ea0177cb'	System	14 Jan 2021 20:58:03
User entered 'No (N)'	System	14 Jan 2021 20:58:03

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-14T14:58:01', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'c8c4d647-b91f-4fb2-85be-7512ea0177cb' User entered '14 Jan 2021 14:58:01'	System	14 Jan 2021 20:58:03

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-21T11:29:32', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0dd9c45b-dfd3-4fb6-98e1-8f8252b341ce' User entered 'No (N)'	System	21 Jan 2021 17:29:46

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-21T11:29:39', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0dd9c45b-dfd3-4fb6-98e1-8f8252b341ce' User entered 'No (N)'	System	21 Jan 2021 17:29:46
	System	21 Jan 2021 17:29:46

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-21T11:29:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0dd9c45b-dfd3-4fb6-98e1-8f8252b341ce' User entered '21 Jan 2021 11:29:43'	System	21 Jan 2021 17:29:46
	System	21 Jan 2021 17:29:46

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-28T10:35:11', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63f22793-9afc-4abe-90d2-8ef909a93dba' User entered 'No (N)'	System	28 Jan 2021 16:35:29

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-28T10:35:22', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63f22793-9afc-4abe-90d2-8ef909a93dba' User entered 'No (N)'	System	28 Jan 2021 16:35:29

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-01-28T10:35:26', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '63f22793-9afc-4abe-90d2-8ef909a93dba' User entered '28 Jan 2021 10:35:26'	System	28 Jan 2021 16:35:29

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-04T15:41:36', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3b65e6d5-ba50-495e-95b9-90884312e8d8'	System	04 Feb 2021 21:41:47
User entered 'No (N)'	System	04 Feb 2021 21:41:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-04T15:41:43', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3b65e6d5-ba50-495e-95b9-90884312e8d8'	System	04 Feb 2021 21:41:47
User entered 'No (N)'	System	04 Feb 2021 21:41:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-04T15:41:46', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '3b65e6d5-ba50-495e-95b9-90884312e8d8' User entered '04 Feb 2021 15:41:46'	System	04 Feb 2021 21:41:47
	System	04 Feb 2021 21:41:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-11T12:08:27', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '79b6e6b3-6cd8-44da-9f63-e7dc29ddd72f'	System	11 Feb 2021 18:11:47
User entered 'No (N)'	System	11 Feb 2021 18:11:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-11T12:08:33', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '79b6e6b3-6cd8-44da-9f63-e7dc29ddd72f'	System	11 Feb 2021 18:11:47
User entered 'No (N)'	System	11 Feb 2021 18:11:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-11T12:08:36', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '79b6e6b3-6cd8-44da-9f63-e7dc29ddd72f' User entered '11 Feb 2021 12:08:36'	System	11 Feb 2021 18:11:47
	System	11 Feb 2021 18:11:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-18T14:59:34', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '9838a0c0-d0a7-4327-977e-a1a093219c31' User entered 'No (N)'	System	18 Feb 2021 20:59:47
	System	18 Feb 2021 20:59:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-18T14:59:41', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '9838a0c0-d0a7-4327-977e-a1a093219c31'	System	18 Feb 2021 20:59:47
User entered 'No (N)'	System	18 Feb 2021 20:59:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-18T14:59:44', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '9838a0c0-d0a7-4327-977e-a1a093219c31' User entered '18 Feb 2021 14:59:44'	System	18 Feb 2021 20:59:47
	System	18 Feb 2021 20:59:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-25T12:23:39-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '892a9b05-0002-40d6-89c8-68a0094f3fbf' User entered 'No (N)'	System	25 Feb 2021 18:24:56
	System	25 Feb 2021 18:24:56

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-25T12:23:46-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '892a9b05-0002-40d6-89c8-68a0094f3fbf' User entered 'No (N)'	System	25 Feb 2021 18:24:56

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-02-25T12:23:51-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '892a9b05-0002-40d6-89c8-68a0094f3fbf' User entered '25 Feb 2021 18:23:51'	System	25 Feb 2021 18:24:56
	System	25 Feb 2021 18:24:56

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-04T14:18:32-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db440afe-d0b8-4497-b775-1f615f3f5670'	System	04 Mar 2021 20:18:47
User entered 'No (N)'	System	04 Mar 2021 20:18:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-04T14:18:38-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db440afe-d0b8-4497-b775-1f615f3f5670'	System	04 Mar 2021 20:18:47
User entered 'No (N)'	System	04 Mar 2021 20:18:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-04T14:18:42-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'db440afe-d0b8-4497-b775-1f615f3f5670'	System	04 Mar 2021 20:18:47
User entered '04 Mar 2021 14:18:42'	System	04 Mar 2021 20:18:47

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-11T13:17:15-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ffd0eff2-1eef-44a4-93be-57703dc473a3'	System	11 Mar 2021 19:17:59
User entered 'No (N)'	System	11 Mar 2021 19:17:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-11T13:17:24-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ffd0eff2-1eef-44a4-93be-57703dc473a3'	System	11 Mar 2021 19:17:59
User entered 'No (N)'	System	11 Mar 2021 19:17:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-11T13:17:28-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'ffd0eff2-1eef-44a4-93be-57703dc473a3'	System	11 Mar 2021 19:17:59
User entered '11 Mar 2021 13:17:28'	System	11 Mar 2021 19:17:59

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-21T20:11:18-05:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '4103d174-dbb2-4b10-b0f3-7f92d9792583'	System	22 Mar 2021 01:15:43
User entered 'No (N)'	System	22 Mar 2021 01:15:43

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-21T20:11:31-05:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '4103d174-dbb2-4b10-b0f3-7f92d9792583'	System	22 Mar 2021 01:15:43
User entered 'No (N)'	System	22 Mar 2021 01:15:43

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-21T20:11:59-05:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '4103d174-dbb2-4b10-b0f3-7f92d9792583'	System	22 Mar 2021 01:15:43
User entered '21 Mar 2021 20:11:59'	System	22 Mar 2021 01:15:43

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-04-01T10:43:42-05:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0e153383-856b-4f48-9cdc-bdb5c686c726'	System	01 Apr 2021 15:44:02
User entered 'No (N)'	System	01 Apr 2021 15:44:02

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-04-01T10:43:49-05:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0e153383-856b-4f48-9cdc-bdb5c686c726'	System	01 Apr 2021 15:44:02
User entered 'No (N)'	System	01 Apr 2021 15:44:02

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-04-01T10:43:59-05:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: '0e153383-856b-4f48-9cdc-bdb5c686c726'	System	01 Apr 2021 15:44:02
User entered '01 Apr 2021 10:43:59'	System	01 Apr 2021 15:44:02

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:13:06

US3442074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:13:06
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:13:06

US3442074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:41:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-04T14:19:01-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd142265c-60fa-4817-a786-e050ff3d9e35'	System	04 Mar 2021 20:19:08
User entered 'No (N)'	System	04 Mar 2021 20:19:08

US3442074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:41:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (288504FD-E041-4B6E-B4C2-81DD7BA451BD)', Time: '2021-03-04T14:19:06-06:00', User OID: 'PatientReportedOutcome (US3442074)', ODM File OID: 'd142265c-60fa-4817-a786-e050ff3d9e35'	System	04 Mar 2021 20:19:08
User entered '04 Mar 2021 14:19:06'	System	04 Mar 2021 20:19:08

US3442074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
DataPoint Verified.		26 Feb 2021 18:05:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 16:52:14

US3442074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
DataPoint Verified.		26 Feb 2021 18:05:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '16 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 16:52:14

US3442074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
DataPoint Verified.		26 Feb 2021 18:05:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 16:52:14

US3442074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
DataPoint Verified.		26 Feb 2021 18:05:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 16:52:14

US3442074

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
DataPoint Verified.		26 Feb 2021 18:05:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 16:52:25

US3442074

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:45:25
User entered '1'	System	16 Nov 2020 16:52:25

US3442074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:05:38
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 00:37:10

US3442074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:05:38
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '7 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 00:37:10

US3442074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:05:38
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 00:37:10

US3442074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:05:38
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 00:37:10

US3442074

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:05:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 00:37:16

US3442074

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User entered '1'	System	08 Dec 2020 00:37:16

US3442074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:06:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:00:04

US3442074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:06:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:00:04

US3442074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:06:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:00:04

US3442074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:06:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:00:04

US3442074

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
DataPoint Verified.		26 Feb 2021 18:06:06
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:00:08

US3442074

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User entered '1'	System	04 Feb 2021 23:00:08

US3442074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:18:21
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:54:44

US3442074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:18:21
User entered '19 Feb 2021'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:54:44

US3442074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:18:21
User entered 'Contact Made (CONTACT MADE)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:54:44

US3442074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:18:21
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:54:44

US3442074

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:18:24
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:54:52

US3442074

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:38:09
User entered '1'	System	08 Mar 2021 20:54:52

US3442074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:23
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:55:26

US3442074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:23
User entered '8 Mar 2021'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:55:26

US3442074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:23
User entered 'Clinic (Clinic)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:55:26

US3442074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered 'VISIT4'	System	08 Mar 2021 20:55:26

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered empty.	System	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered empty.	System	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered empty.	System	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered empty.	System	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 04:54:05
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered empty.	System	30 Mar 2021 18:18:57

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49

US3442074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49

US3442074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:27
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:55:49

US3442074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:27
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:55:49

US3442074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Mar 2021 20:17:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:57:01

US3442074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:35
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:57:01

US3442074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:35
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:57:01

US3442074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered empty.	System	08 Mar 2021 20:57:01

US3442074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:17:38
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Mar 2021 20:57:40

US3442074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:49
User entered '1'	System	08 Mar 2021 20:57:40

US3442074

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:06:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:22:44

US3442074

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:06:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:22:44

US3442074

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:06:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:22:44

US3442074

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 17:22:44

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:18
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:36:50

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:18
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:36:50

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:18
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:18
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:18
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:18
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:18
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '1'	System	20 Jan 2021 17:23:23

US3442074

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '1'	System	20 Jan 2021 17:23:23

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered empty.	System	20 Jan 2021 17:25:09
DataPoint set to visible.	System	20 Jan 2021 17:23:23

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered empty.	System	20 Jan 2021 17:25:09
DataPoint set to visible.	System	20 Jan 2021 17:23:23

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User accepted default value 'Pre-Dose (PREDOSE)'		20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '08:43'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '19 Jan 2021 08:43'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '80'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'bpm'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '12'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'breaths/min'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '118'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'mmHg'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '71'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'mmHg'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered empty.	System	20 Jan 2021 17:25:09
DataPoint set to visible.	System	20 Jan 2021 17:23:23

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User accepted default value 'Post-Dose (POSTDOSE)'		20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '10:05'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '19 Jan 2021 10:05'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '91'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'bpm'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '12'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'breaths/min'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '148'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'mmHg'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '88'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:25:09

US3442074

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'mmHg'	System	20 Jan 2021 17:25:09

US3442074

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:04

US3442074

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:04

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'mRNA-1273'	System	20 Jan 2021 17:26:49
DataPoint set to visible.	System	20 Jan 2021 17:23:23

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '09:33'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '19 Jan 2021 09:33'	System	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:00
User entered 'ONCE'	System	20 Jan 2021 17:26:49

US3442074

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 17:26:49

US3442074

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:04

US3442074

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:04

US3442074

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '08:47'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:04

US3442074

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '19 Jan 2021 08:47'	System	20 Jan 2021 17:27:04

US3442074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:44
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:23

US3442074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:44
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:23

US3442074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:07:44
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '08:49'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:23

US3442074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '19 Jan 2021 08:49'	System	20 Jan 2021 17:27:23

US3442074

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

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
DataPoint Verified.		26 Feb 2021 18:08:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:27

US3442074

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

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:01:19
User entered '1'	System	20 Jan 2021 17:27:27

US3442074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:52
DataPoint Verified.		26 Feb 2021 18:08:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:03

US3442074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:52
DataPoint Verified.		26 Feb 2021 18:08:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:03

US3442074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:52
DataPoint Verified.		26 Feb 2021 18:08:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:03

US3442074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:52
DataPoint Verified.		26 Feb 2021 18:08:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:03

US3442074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:52
DataPoint Verified.		26 Feb 2021 18:09:03
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:55:56

US3442074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:52
User entered '1'	System	26 Jan 2021 19:55:56

US3442074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:52
User entered '1'	System	26 Jan 2021 19:55:56
DataPoint set to visible.	System	26 Jan 2021 19:55:56

US3442074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:55:15

US3442074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '22 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:55:15

US3442074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:55:15

US3442074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'OLD29'	System	22 Feb 2021 17:55:15

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User accepted default value 'Pre-Dose (PREDOSE)'	Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '22 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '10:00'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered '22 Feb 2021 10:00'	System	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '98.5' F	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '105'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'bpm'	System	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '16'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'breaths/min'	System	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '111'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'mmHg'	System	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '77'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'mmHg'	System	22 Feb 2021 17:58:00

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User accepted default value 'Post-Dose (POSTDOSE)'	Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '22 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '11:08'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered '22 Feb 2021 11:08'	System	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '99.4' F	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '96'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'bpm'	System	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '14'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'breaths/min'	System	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '117'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'mmHg'	System	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:21
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '86'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'mmHg'	System	22 Feb 2021 17:59:30

US3442074

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:47

US3442074

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '22 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 17:59:47

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'mRNA-1273'	System	22 Feb 2021 18:02:14
DataPoint set to visible.	System	26 Jan 2021 19:55:56

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '22 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '10:28'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered '22 Feb 2021 10:28'	System	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:09:33
User entered 'ONCE'	System	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 18:02:14

US3442074

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
DataPoint Verified.		26 Feb 2021 18:10:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:02:23

US3442074

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:59
User entered '1'	System	22 Feb 2021 18:02:23

US3442074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:12:41
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:16:45
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	04 Mar 2021 01:06:43

US3442074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:12:41
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:16:45
User entered '1 Mar 2021'	Oluwatosin Akingbala (b) (4)	04 Mar 2021 01:06:43

US3442074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:12:41
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:16:45
User entered 'Contact Made (CONTACT MADE)'	Oluwatosin Akingbala (b) (4)	04 Mar 2021 01:06:43

US3442074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:12:41
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Mar 2021 20:16:45
User entered empty.	Oluwatosin Akingbala (b) (4)	04 Mar 2021 01:06:43

US3442074

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:12:41
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:16:48
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	04 Mar 2021 01:07:06

US3442074

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:12:41
User entered '1'	System	04 Mar 2021 01:07:06

US3442074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:29
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:01:20

US3442074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:29
User entered '22 Mar 2021'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:01:20

US3442074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:29
User entered 'Clinic (Clinic)'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:01:20

US3442074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User entered 'OLD57'	System	23 Mar 2021 00:01:20

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered '22 Mar 2021'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered '08:37'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User entered '22 Mar 2021 08:37'	System	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered '98.3' F	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered 'Oral (Oral)'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered empty.	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered '87'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User entered 'bpm'	System	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered '14'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User entered 'breaths/min'	System	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered '129'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User entered 'mmHg'	System	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:44
User entered '84'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User entered 'mmHg'	System	23 Mar 2021 00:02:28

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09

US3442074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09

US3442074

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:52
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:03:03

US3442074

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:57:52
User entered empty.	Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:03:03

US3442074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
DataPoint Verified.		14 Apr 2021 20:20:57
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:03:47

US3442074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
DataPoint Verified.		14 Apr 2021 20:20:57
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:03:47

US3442074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
DataPoint Verified.		14 Apr 2021 20:20:57
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	23 Mar 2021 00:03:47

US3442074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:09
User entered empty.	System	23 Mar 2021 00:03:47

US3442074

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:41:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:09:17
DataPoint Verified.		26 Feb 2021 18:11:44
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 19:56:17
User entered 'Yes (Y)' reason for change: Data Entry Error		26 Jan 2021 19:56:17
DataPoint Verified.		17 Sep 2020 21:41:19
User entered 'No (N)'	Melody Dufrene (b) (4)	02 Sep 2020 23:17:09
	(b) (4)	

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:20:47
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Per PI/Sub-I symptom was an ongoing solicited symptom. So illness visit was not conducted ' (Site from DM).	John Villegas (b) (4)	18 Mar 2021 21:13:09
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 11:32:25
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 19:57:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 19:57:57
Data point term sent to Coder	System	26 Jan 2021 19:57:01
User entered 'nausea'	(b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'No (N)' reason for change: New Information	(b) (4)	22 Feb 2021 20:11:21
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '10 Feb 2021' reason for change: New Information	(b) (4)	22 Feb 2021 20:11:21
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '1'	(b) (4) (u) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	22 Feb 2021 20:11:21
New Information	Oluwatosin Akingbala	22 Feb 2021 20:11:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:11:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 19:56:59

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:49
User entered 'USA-US017-2021-mRNA-1273-P301000010'	System	07 Apr 2021 18:46:08
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 18:46:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:10:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:10:05
Data point term sent to Coder	System	28 Apr 2021 21:10:03
User entered 'ISCHEMIC CEREBROVASCULAR ACCIDENT (CVA) (HCC)' reason for change: Data Entry Error	Alma Guel (b) (4)	28 Apr 2021 21:09:04
Data point term sent to Coder	System	28 Apr 2021 21:08:02
DataPoint Un-verified.	Alma Guel (b) (4)	28 Apr 2021 21:07:50
Coding entries removed.	Alma Guel (b) (4)	28 Apr 2021 21:07:50
Signature has been broken.	Alma Guel (b) (4)	28 Apr 2021 21:07:50
User entered 'Ischemic cerebrovascular accident' reason for change: Data Entry Error	Alma Guel (b) (4)	28 Apr 2021 21:07:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:19:53
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:39:48
Data point term sent to Coder	System	07 Apr 2021 14:38:15
User entered 'Stroke'	Alma Guel (b) (4)	07 Apr 2021 14:37:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '02 Apr 2021'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '06 Apr 2021'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Grade 4 (Grade 4)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '1'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '0'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 00:09:53
User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	William Seger (b) (4)	13 Apr 2021 15:19:53
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	(b) (4)	07 Apr 2021 14:48:32
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	07 Apr 2021 14:48:32
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Apr 2021 14:37:51
User entered '0'	Alma Guel (b) (4)	07 Apr 2021 14:37:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '02 Apr 2021'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '06 Apr 2021'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:54
DataPoint Un-verified.		14 Apr 2021 20:27:21
DataPoint Verified.		14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 03:24:02
User entered 'No (N)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	09 Apr 2021 21:02:02
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'updated, per medical record subject went to hospices ' (Site from System).	John Villegas (b) (4) (b) (4)	09 Apr 2021 21:01:31
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	07 Apr 2021 14:37:51
User entered 'Unknown (UNK)'	Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '0'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '0'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '0'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of [study drug] was given on 22 Feb 2021, please update the action taken with [study drug] from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:05:28
Query 'PV Query: As the last dose of [study drug] was given on 22 Feb 2021, please update the action taken with [study drug] from none to not applicable. ' answered with 'updated' (Site from Safety).	Alma Guel (b) (4)	20 Apr 2021 22:02:22
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:00:56
DataPoint Un-verified.	Alma Guel (b) (4)	20 Apr 2021 22:00:32
Signature has been broken.	Alma Guel (b) (4)	20 Apr 2021 22:00:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Alma Guel (b) (4)	20 Apr 2021 22:00:32
User opened query 'PV Query: As the last dose of [study drug] was given on 22 Feb 2021, please update the action taken with [study drug] from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 00:10:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'None (NONE)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '1'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '0'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '0'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Fatal (FATAL)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 00:10:15
User opened query 'PV Query: Please confirm the cause of death. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 00:09:45
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so. ' (Site from Safety).		16 Apr 2021 00:09:38
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).		16 Apr 2021 00:09:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		16 Apr 2021 00:09:24
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		16 Apr 2021 00:09:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Subject suffered from a stroke on 02Apr2021 and was hospitalized. Subject passed away on 06Apr2021. Medical records have been requested.'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 14:37:51

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:21:33
User entered 'USA-US017-2021-mRNA-1273-P301000011'	System	29 Apr 2021 15:21:26
User entered 'New'	(b) (4), (b) (6)	29 Apr 2021 15:21:26

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Diabetic ketoacidosis, LLT: Diabetic ketoacidosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 21:00:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 21:00:07
Data point term sent to Coder	System	28 Apr 2021 20:49:45
User entered 'Diabetic Ketoacidosis'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	03 May 2021 13:35:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:50:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:50:12
User entered 'UN Mar 2021' (non-conformant).	Alma Guel (b) (4)	28 Apr 2021 20:50:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:49:08
User entered 'un 2021' (non-conformant).	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	03 May 2021 13:35:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:49:08
User entered 'un Mar 2021' (non-conformant).	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	03 May 2021 13:35:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:49:08
User entered 'un Mar 2021' (non-conformant).	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	03 May 2021 13:35:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:49:08
User entered 'un Mar 2021' (non-conformant).	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 09:30:17
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'number of days is unknown' (Site from System).	Alma Guel (b) (4)	28 Apr 2021 20:50:39
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	28 Apr 2021 20:50:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:50:12
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	28 Apr 2021 20:50:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Apr 2021 20:49:08
User entered 'unk' (non-conformant).	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[None](#)

Audit	User	Time (GMT)
User entered '1'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Narrative](#)

Audit	User	Time (GMT)
User entered 'during review of medical records for SAE "Stroke", the following was noted: "Patient was recently admitted a few weeks ago to another hospital for DKA, which required ICU admission." The subject is now deceased and we have no other information regarding hospital and/or timelines of event.'	Alma Guel (b) (4)	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 20:49:08

US3442074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 20:49:08

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:41:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:15:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 21:42:49
User entered 'Yes (Y)'	Melody Dufrene (b) (4)	25 Aug 2020 16:38:48

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:43:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:41:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:41:34
Data point term sent to Coder	System	25 Aug 2020 16:40:13
User entered 'METFORMIN'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:43:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:43:11
User entered 'TYPE II DIABETES'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:43:12
User entered '750'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:43:14
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:43:20
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:43:21
User entered 'twice daily (BID)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:03
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:05
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:10
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:12
User entered 'UN UNK 2009'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:14
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:18
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:22
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:24
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 16:39:42

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:44:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:44:42
Data point term sent to Coder	System	25 Aug 2020 16:43:22
User entered 'SYMBICORT'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:42
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:45:56
User entered 'COPD'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:21
User entered '2'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:23
User entered 'puff (PUFF)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:26
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:31
User entered 'as needed (PRN)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:45
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:46
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:43:39
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	17 Sep 2020 21:47:51
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	25 Aug 2020 16:43:39
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	25 Aug 2020 16:42:38
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:47:52
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 16:42:38

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:48:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:00:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:00:38
Data point term sent to Coder	System	25 Aug 2020 16:45:25
User entered 'BENICAL/HCTZ'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:48:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:48:13
User entered 'HYPERTENSION'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:48:20
User entered '40/25'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:48:24
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:48:27
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:10
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:12
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:15
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:16
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:18
User entered 'UN Feb 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:20
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:22
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:24
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:51:27
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 16:44:46

US3442074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:41:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:33:07
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 23:17:13

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:42

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:13:34
DataPoint Verified.		14 Apr 2021 20:28:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '06 Apr 2021'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 16:10:21

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:42

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:13:34
DataPoint Verified.		14 Apr 2021 20:28:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Death (DEATH)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 16:10:21

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:42

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)	27 Apr 2021 15:13:34
DataPoint Verified.		14 Apr 2021 20:28:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Alma Guel (b) (4)	07 Apr 2021 16:10:21

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:42

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:13:34
DataPoint Verified.		14 Apr 2021 20:28:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Adverse event (ADVERSE EVENT)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 16:10:21

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:42

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:13:34
DataPoint Verified.		14 Apr 2021 20:28:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered empty.	(b) (4) Alma Guel (b) (4)	07 Apr 2021 16:10:21

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:42

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:13:34
DataPoint Verified.		14 Apr 2021 20:28:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '06 Apr 2021'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 16:10:21

US3442074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:42

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:13:34
DataPoint Verified.		14 Apr 2021 20:28:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered 'Unknown (UNK)'	(b) (4) Alma Guel (b) (4)	07 Apr 2021 16:10:21

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'USA-US017-2021-MRNA-1273-P301000010'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 22:16:20
DataPoint Verified.		19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'William'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Seger'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User closed query 'Please change the street number to 4504' (Site from CRA).		19 Apr 2021 17:02:33
Query 'Please change the street number to 4504' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	15 Apr 2021 16:35:05
Un-reviewed for Safety.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
Signature has been broken.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User opened query 'Please change the street number to 4504' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:26:19
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '4505 Boat Club Road, Suite 400A'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Fort Worth'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User entered empty.	Alma Guel (b) (4)	15 Apr 2021 16:34:38

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '76135'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 14:07:58
User entered 'US'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 15:41:20
User entered '3'	System	21 Apr 2021 15:08:55
User entered '2'	System	12 Apr 2021 14:08:14
User entered '1'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'USA-US017-2021-MRNA-1273-P301000010'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 22:16:20
DataPoint Verified.		19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'William'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Seger'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User closed query 'Please change the street number to 4504' (Site from CRA).		19 Apr 2021 17:02:33
Query 'Please change the street number to 4504' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	15 Apr 2021 16:35:05
Un-reviewed for Safety.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
Signature has been broken.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User opened query 'Please change the street number to 4504' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:26:19
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '4505 Boat Club Road, Suite 400A'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Fort Worth'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User entered empty.	Alma Guel (b) (4)	15 Apr 2021 16:34:38

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '76135'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:07:58
User entered 'US'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 15:41:20
User entered '3'	System	21 Apr 2021 15:08:55
User entered '2'	System	12 Apr 2021 14:08:14
User entered '1'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '07/Apr/2021 11:46'	(b) (4) System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:07:58
User entered '1'		07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'USA-US017-2021-MRNA-1273-P301000010'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 22:16:20
DataPoint Verified.		19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'William'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Sege'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User closed query 'Please change the street number to 4504' (Site from CRA).		19 Apr 2021 17:02:33
Query 'Please change the street number to 4504' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	15 Apr 2021 16:35:05
Un-reviewed for Safety.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
Signature has been broken.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User opened query 'Please change the street number to 4504' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:26:19
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '4505 Boat Club Road, Suite 400A'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Fort Worth'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User entered empty.	Alma Guel (b) (4)	15 Apr 2021 16:34:38

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '76135'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:07:58
User entered 'US'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 15:41:20
User entered '3'	System	21 Apr 2021 15:08:55
User entered '2'	System	12 Apr 2021 14:08:14
User entered '1'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:41:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '12/Apr/2021 14:08'	(b) (4) System	12 Apr 2021 14:08:14

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:41:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
DataPoint Verified.		19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:08:14

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'USA-US017-2021-MRNA-1273-P301000010'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 22:16:20
DataPoint Verified.		19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'William'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Seger'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User closed query 'Please change the street number to 4504' (Site from CRA).		19 Apr 2021 17:02:33
Query 'Please change the street number to 4504' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	15 Apr 2021 16:35:05
Un-reviewed for Safety.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
Signature has been broken.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User opened query 'Please change the street number to 4504' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:26:19
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '4505 Boat Club Road, Suite 400A'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Fort Worth'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User entered empty.	Alma Guel (b) (4)	15 Apr 2021 16:34:38

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '76135'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:07:58
User entered 'US'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 15:41:20
User entered '3'	System	21 Apr 2021 15:08:55
User entered '2'	System	12 Apr 2021 14:08:14
User entered '1'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:41:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:58:14
User entered '21/Apr/2021 08:08'	System	21 Apr 2021 15:08:55

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:41:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:58:14
User entered '1'		21 Apr 2021 15:08:55

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'USA-US017-2021-MRNA-1273-P301000010'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 22:16:20
DataPoint Verified.		19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Yes (Y)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'No (N)'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'William'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Seger'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User closed query 'Please change the street number to 4504' (Site from CRA).		19 Apr 2021 17:02:33
Query 'Please change the street number to 4504' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	15 Apr 2021 16:35:05
Un-reviewed for Safety.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
Signature has been broken.	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	15 Apr 2021 16:34:38
User opened query 'Please change the street number to 4504' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:26:19
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '4505 Boat Club Road, Suite 400A'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered 'Fort Worth'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:41:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:02:37
User entered empty.	Alma Guel (b) (4)	15 Apr 2021 16:34:38

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:46:22
User entered '76135'	System	07 Apr 2021 18:46:08

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:02:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 14:07:58
User entered 'US'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 15:41:20
User entered '3'	System	21 Apr 2021 15:08:55
User entered '2'	System	12 Apr 2021 14:08:14
User entered '1'	System	07 Apr 2021 18:46:29

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:41:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 22:15:58
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
User entered '29/Apr/2021 10:41'	(b) (4) System	29 Apr 2021 15:41:20

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:41:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 22:15:58
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:41:20

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:02
User entered 'USA-US017-2021-MRNA-1273-P301000011'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Yes (Y)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Yes (Y)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'William'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Seger'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	29 Apr 2021 15:22:07
User entered '4504 Boat Club Road, Suite 400A'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Fort Worth'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Apr 2021 15:22:07
User entered '76135'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
User entered 'US'	(b) (4) System	29 Apr 2021 15:22:22

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 15:22:22

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:02
User entered 'USA-US017-2021-MRNA-1273-P301000011'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Yes (Y)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Yes (Y)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'No (N)'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'William'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Seger'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Apr 2021 15:22:07
User entered '4504 Boat Club Road, Suite 400A'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:07
User entered 'Fort Worth'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Apr 2021 15:22:07
User entered '76135'	System	29 Apr 2021 15:21:26

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
User entered 'US'	(b) (4) System	29 Apr 2021 15:22:22

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 15:22:22

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
User entered '29/Apr/2021 11:22'	(b) (4) System	29 Apr 2021 15:22:22

US3442074

Folder: SAE USA-US017-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:55
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:22:22