

US3432208 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:35:02

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US3432208

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

[Participant ID](#)

US3432208

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

US3432208

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 AUG 2020

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

Folder OID SCRN

US3432208

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3432208

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Date of Informed Consent (*dd MMM yyyy*) 20 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3432208

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 02:00:58

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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) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432208

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	DYSPEPSIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3432208

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	BARIATRIC SURGERY
Start date (dd MMM yyyy)	31 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	31 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

US3432208

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	SPINE CORRECTIVE SURGERY
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	17 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3432208

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	CLINDAMYCIN ALLERGY (RASH)
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Condition	CIPROFLOX (RASH)
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432208

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 20 AUG 2020

Time of assessment (00:00-23:59) 9:40 (24 HR)

Vital Signs Date and Time (derived) 20 AUG 2020 9:40

Height (xxx.x) 161.6 cm

Weight (xxx.x) 78.5 kg

BMI (xxx.x) 30.05986 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

20 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: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:00:58

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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) 19 Feb 2021 02:00:58

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 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) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 144051

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) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

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) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	9:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 9:40
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	53 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:16 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:16
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	51 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

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) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 11:45 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 11:45

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) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 20 AUG 2020

Collection time (*00:00-23:59*) 10:29 (24 HR)

Collection date and time (derived) 20 AUG 2020 10:29

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Collection date (<i>dd MMM yyyy</i>)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:16	20 AUG 2020 10:16
Nasopharyngeal Swab 2	No		

US3432208

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 97.4 °F

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

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

PC Time Stamp 20 AUG 2020 12:22

PC Open Date & Time 20 AUG 2020 12:05

PC Close Date & Time 20 AUG 2020 14:35

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 20 AUG 2020 17:26
PC Open Date & Time 20 AUG 2020 15:30
PC Close Date & Time 21 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 AUG 2020 12:12
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 AUG 2020 08:18
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 11:11
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 AUG 2020 07:59
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 AUG 2020 07:51
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 AUG 2020 07:34
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 AUG 2020 12:23

PC Open Date & Time

20 AUG 2020 12:05

PC Close Date & Time

20 AUG 2020 14:35

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

20 AUG 2020 17:26

PC Open Date & Time

20 AUG 2020 15:30

PC Close Date & Time

21 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

21 AUG 2020 12:13

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	23 AUG 2020 08:19
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 4

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

24 AUG 2020 11:11

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 5

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 07:59
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 6

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

26 AUG 2020 07:51

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 7

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

27 AUG 2020 07:34

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

No

Yes

PC Time stamp	20 AUG 2020 12:24
PC Open Date & Time	20 AUG 2020 12:05
PC Close Date & Time	20 AUG 2020 14:35

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

No
Yes

PC Time stamp	20 AUG 2020 17:27
PC Open Date & Time	20 AUG 2020 15:30
PC Close Date & Time	21 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	21 AUG 2020 12:14
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 08:19
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 11:12
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

Yes

PC Time stamp	25 AUG 2020 08:00
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 07:51
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	27 AUG 2020 07:34
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 AUG 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 17 SEP 2020

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

Folder OID VISIT2

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	8:26 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 8:26
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:19 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:19
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3432208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 09:49 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 09:49

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

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 17 SEP 2020

Collection time (*00:00-23:59*) 09:30 (24 HR)

Collection date and time (derived) 17 SEP 2020 09:30

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Collection date (<i>dd MMM yyyy</i>)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	17 SEP 2020 09:35
Nasopharyngeal Swab 2	No		

US3432208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 98.6 °F

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

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

PC Time Stamp 17 SEP 2020 10:26

PC Open Date & Time 17 SEP 2020 10:09

PC Close Date & Time 17 SEP 2020 12:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 18 SEP 2020 09:50
PC Open Date & Time 17 SEP 2020 13:34
PC Close Date & Time 18 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 11:21
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 08:32
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 22:36
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 SEP 2020 13:17
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 08:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 SEP 2020 10:22
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 SEP 2020 10:26

PC Open Date & Time

17 SEP 2020 10:09

PC Close Date & Time

17 SEP 2020 12:39

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

18 SEP 2020 09:51

PC Open Date & Time

17 SEP 2020 13:34

PC Close Date & Time

18 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 2

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	19 SEP 2020 11:21
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 3

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

20 SEP 2020 08:32

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 4

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	20 SEP 2020 22:37
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	21 SEP 2020 13:17
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

23 SEP 2020 08:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 7

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

24 SEP 2020 10:22

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

No
Yes

PC Time stamp	17 SEP 2020 10:27
PC Open Date & Time	17 SEP 2020 10:09
PC Close Date & Time	17 SEP 2020 12:39

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

No

Yes

PC Time stamp	18 SEP 2020 09:51
PC Open Date & Time	17 SEP 2020 13:34
PC Close Date & Time	18 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 11:22
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 08:33
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 22:37
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 13:18
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 08:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 10:23
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 OCT 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 OCT 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	8:22 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 8:22
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	97 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3432208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 13 OCT 2020

Collection time (*00:00-23:59*) 8:56 (24 HR)

Collection date and time (derived) 13 OCT 2020 8:56

US3432208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 29 OCT 2020 06:55:05

Patient Cloud Open Date & Time 27 OCT 2020 00:01

Patient Cloud Close Date & Time 31 OCT 2020 23:59

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 03 NOV 2020 00:02:15

Patient Cloud Open Date & Time 03 NOV 2020 00:01

Patient Cloud Close Date & Time 07 NOV 2020 23:59

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 13:19:07
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 08 DEC 2020 12:53:43

Patient Cloud Open Date & Time 05 DEC 2020 00:01

Patient Cloud Close Date & Time 09 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 17:21:15
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 03:24:21
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 28 DEC 2020 12:01:20

Patient Cloud Open Date & Time 26 DEC 2020 00:01

Patient Cloud Close Date & Time 30 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 19:14:44
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 09 JAN 2021 05:42:25

Patient Cloud Open Date & Time 09 JAN 2021 00:01

Patient Cloud Close Date & Time 13 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 08:15:18
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 01:06:58
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 07:51:58
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 20:10:09
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 13 FEB 2021 07:40:52

Patient Cloud Open Date & Time 13 FEB 2021 00:01

Patient Cloud Close Date & Time 17 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 23 FEB 2021 12:05:11

Patient Cloud Open Date & Time 20 FEB 2021 00:01

Patient Cloud Close Date & Time 24 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 01:31:28
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 00:02:57
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 13 MAR 2021 00:29:57

Patient Cloud Open Date & Time 13 MAR 2021 00:01

Patient Cloud Close Date & Time 17 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 00:01:41
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 27 MAR 2021 00:15:18

Patient Cloud Open Date & Time 27 MAR 2021 00:01

Patient Cloud Close Date & Time 31 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 08:52:30
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 01:11:01
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 00:23:47
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 20:30:51
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 14:16:01
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 264

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 271

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 278

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 285

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 292

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 299

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 306

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 313

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 320

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 327

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 334

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 341

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 348

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 355

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 362

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 369

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 376

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 383

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 390

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 397

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 404

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#) 29 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 411

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#) 02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 06 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 418

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#) 09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 13 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 425

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 432

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 439

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 446

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 453

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 460

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 467

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 474

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 481

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 488

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 495

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 29 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 502

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 509

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 12 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 516

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 523

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#) 22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 26 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 530

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

29 JAN 2022 00:01

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02 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 537

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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Date and time of submission

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05 FEB 2022 00:01

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09 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 544

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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16 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 551

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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Date and time of submission

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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 558

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 565

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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09 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 572

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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16 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 579

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 586

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

US3432208

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

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30 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 593

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

US3432208

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Date and time of submission

[Patient Cloud Open Date & Time](#) 02 APR 2022 00:01

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US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 600

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

US3432208

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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Date and time of submission	
Patient Cloud Open Date & Time	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 607

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 614

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 621

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 628

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 635

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

US3432208

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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 642

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 649

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 656

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 663

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 670

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 677

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 684

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 691

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 698

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 705

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 712

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 719

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 726

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#) 13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 17 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 733

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 740

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 747

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 754

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 761

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 768

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#) 24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#) 28 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 775

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 05 OCT 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 782

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 789

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

DAY 796

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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](#) 22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 26 OCT 2022 23:59

US3432208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:35:02

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
Yes	Yes	02 MAR 2021 18:13:44

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 DEC 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 JAN 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 MAR 2021

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

Folder OID VISIT4

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	7:27 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 7:27
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

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.

US3432208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 26 MAR 2021

Collection time (*00:00-23:59*) 7:29 (24 HR)

Collection date and time (derived) 26 MAR 2021 7:29

US3432208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 11:07:22

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 APR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:07:22

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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 _____

US3432208

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3432208

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:35:02

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3432208

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:35:02

Generate Next COVID-19 Assessment

Yes

No

US3432208

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 25 JAN 2021

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

Folder OID UNBLND_DECIDE

US3432208

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	25 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3432208

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3432208

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	07:22 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 07:22
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3432208

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 08:51
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 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

US3432208

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3432208

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 08:21 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 08:21

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

US3432208

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 25 JAN 2021

Collection time (*00:00-23:59*) 07:28 (24 HR)

Collection date and time (derived) 25 JAN 2021 07:28

US3432208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 25 JAN 2021

Collection time (*00:00 - 23:59*) 07:33

Collection Date and Time (derived) 25 JAN 2021 07:33

US3432208

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 FEB 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:00:58

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3432208

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 FEB 2021

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

Folder OID OLD29

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	16:05 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 16:05
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	085 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	069 mmHg
Diastolic Blood Pressure units	MMHG

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	17:06 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 17:06
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	077 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	086 mmHg
Diastolic Blood Pressure units	MMHG

US3432208

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3432208

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

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) 26 FEB 2021

What was the treatment time? (00:00-23:59) 16:30 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 16:30

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

US3432208

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 MAR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432208

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 MAR 2021

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

Folder OID OLD57

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 26 MAR 2021

Time of assessment (*00:00-23:59*) 7:27 (24 HR)

Vital Signs Date and Time (derived) 26 MAR 2021 7:27

Temperature (*xxx.x*) 36.9 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) 71 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 12 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 130 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 82 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3432208

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

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.

US3432208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 MAR 2021

Collection time (*00:00-23:59*) 7:29 (24 HR)

Collection date and time (derived) 26 MAR 2021 7:29

US3432208

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

AEID USA-US078-2020-MRNA-1273-P30
1000004

Adverse event SPINAL STENOSIS

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) 07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 05 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 02 OCT 2020

Hospital Discharge Date (dd MMM yyyy) 05 OCT 2020

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Apr 2021 20:40:45

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Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

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

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

AN MRI OF C-SPINE ON 9/7/2020 REVEALED CANAL STENOSIS AT C5-7; HE UNDERWENT AN ANTERIOR CERVICAL DISECTOMY + FUSION ON 10/2/2020; POST OP COURSE UNREMARKABLE AND DISCHARGED ON 10/5/2020. PARTICIPANT REPORTED THIS TO SITE ON 13OCT2020 DURING THEIR SCHEDULED VISIT 3.

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

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

AEID

Adverse event

ANXIETY RELATED TO SPINAL
STENOSIS PROCEDURE

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)

05 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes
No

If not Ongoing, end date (dd MMM yyyy)

06 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Apr 2021 20:40:45

Generated On: 09 Jun 2021 17:35:02

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

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

Yes

No

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication NORVASC

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2000

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication METFORMIN

Prophylaxis Yes
No

Indication TYPE II DIABETES

Dose per administration 500

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2018

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication SERTRALINE

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication OMEPRAZOLE

Prophylaxis Yes
No

Indication DYSPEPSIA

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

TWICE A DAY AND AS NEEDED

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

- 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 2017

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication LORAZEPAM

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 5 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 6 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication HYDROMORPHONE

Prophylaxis Yes
No

Indication PAIN FROM SPINE SURGERY

Dose per administration 0.2-0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 2 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication HYDROMORPHONE

Prophylaxis Yes
No

Indication PAIN FROM SPINE SURGERY

Dose per administration 2-4

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

EVERY 3 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 4 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 6 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication OXYCODONE

Prophylaxis Yes
No

Indication PAIN FROM SPINE SURGERY

Dose per administration 5-10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 4 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication ZOFRAN

Prophylaxis Yes
No

Indication CON MEDICATION RELATED TO
PROCEDURE FOR AE #1 SPINAL
STENOSIS

Dose per administration 4

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

EVERY 6 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 06 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication ZOFRAN

Prophylaxis Yes
No

Indication NAUSEA

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

EVERY 6 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 5 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication CON MEDICATION RELATED TO
PROCEDURE FOR AE #1 SPINAL
STENOSIS

Dose per administration 650

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

EVERY 6 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 6 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication DULCOLAX

Prophylaxis Yes
No

Indication CON MEDICATION RELATED TO
PROCEDURE FOR AE #1 SPINAL
STENOSIS

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input checked="" type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 6 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication COLACE

Prophylaxis Yes
No

Indication CONSTIPATION

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 2 OCT 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) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication HYDROCODONE/
ACETAMINOPHEN

Prophylaxis Yes
No

Indication PAIN FROM SURGERY FOR
SPINAL STENOSIS

Dose per administration 7.5-325

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

EVERY 6 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 05 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

Name of Medication LIDOCAINE PATCH (4%)

Prophylaxis Yes
No

Indication PAIN FROM SURGERY FOR SPINAL STENOSIS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify APPLICATION

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Apr 2021 11:07:21

Generated On: 09 Jun 2021 17:35:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 4 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 06 OCT 2020

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

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 02:00:35

Generated On: 09 Jun 2021 17:35:02

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	DISCECTOMY ANTERIOR CERVICAL SPINE FUSION	Adverse Event	
07 SEP 2020	CERVICAL SPINE MRI	Adverse Event	

US3432208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:35:02

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Due to SARS-COV-2

Other

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

US3432208

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:35:02

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

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*)

Was autopsy performed?

Yes

No

Unknown

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

SAEID	USA-US078-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

SAEID	USA-US078-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/OCT/2020 08:02
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.	<input checked="" type="checkbox"/> True

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

SAEID	USA-US078-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/OCT/2020 11:08
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.	<input checked="" type="checkbox"/> True

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

SAEID	USA-US078-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	
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.	False

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

SAEID	USA-US078-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 13:46
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.	<input checked="" type="checkbox"/> True

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

SAEID	USA-US078-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 17:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 02:00:36

Generated On: 09 Jun 2021 17:35:02

SAEID	USA-US078-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 00:19
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.	<input checked="" type="checkbox"/> True

Audit

US3432208 (Prod: Brigham and Womens Hospital)

US3432208

Form: Participant Creation

Generated On: 09 Jun 2021 17:35:02

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:00:36
User entered 'US3432208'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 13:34:31

US3432208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:26:46

US3432208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:34:32

US3432208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:26:46

US3432208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'SCRN'	System	20 Aug 2020 14:26:46

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:34:33

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '54'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'YEARS'	System	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '54'	System	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Male (M)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '1'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:02

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Aug 2020'	System	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2020'	System	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Amendment 2 (2)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:34:32

US3432208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '1'	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:35:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:17:17

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:19:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:19:20
Data point term sent to Coder	System	20 Aug 2020 17:18:40
User entered 'Hypertension'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'un UNK 2000'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 17:18:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 17:18:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 17:18:00
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jan 2000'	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2000'	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User coded data point as SOC: Metabolism and nutrition disorders, HLG: 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)	20 Aug 2020 17:20:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:20:26
Data point term sent to Coder	System	20 Aug 2020 17:19:42
User entered 'Type II Diabetes'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'un UNK 2018'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jan 2018'	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2018'	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:20:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:20:24
Data point term sent to Coder	System	20 Aug 2020 17:19:43
User entered 'Depression'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'un UNK 2015'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jan 2015'	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2015'	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Dyspepsia - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:21:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:21:21
Data point term sent to Coder	System	20 Aug 2020 17:20:45
User entered 'Dyspepsia'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'un UNK 2017'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jan 2017'	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2017'	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Metabolic surgery, LLT: Bariatric surgery - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:22:28
Data point term sent to Coder	System	20 Aug 2020 17:21:51
User entered 'Bariatric surgery'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '31 Oct 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '31 Oct 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Oct 2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Oct 2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:56:16
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Spinal operation - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 11:44:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 11:44:30
Data point term sent to Coder	System	22 Oct 2020 00:17:42
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Megan Powell (b) (4)	22 Oct 2020 00:17:04
Coding entries removed.	Megan Powell (b) (4)	22 Oct 2020 00:16:59
User entered 'SPINE CORRECTIVE SURGERY' reason for change: Data Entry Error	Megan Powell (b) (4)	22 Oct 2020 00:16:59
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 04:28:37
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Spinal operation - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:24:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:24:29
Data point term sent to Coder	System	20 Aug 2020 17:22:53

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

[Condition](#)

Audit	User	Time (GMT)
User entered 'Spine surgery'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Jun 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Jun 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jun 2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jun 2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User closed query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:21:46
Query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' answered with 'Per clinician, the presentation of this allergy is a rash.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 16:34:12
User opened query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 04:29:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:11:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:11:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:55:36
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:55:36
Data point term sent to Coder	System	20 Aug 2020 17:22:54
User entered 'Clindamycin allergy (rash)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'un UNK 2015'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jan 2015'	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2015'	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Drug rash - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:41:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:41:01
User closed query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:22:12
Query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' answered with 'Per clinician, the presentation of this allergy is a rash.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 16:34:23
User opened query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 04:29:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:10:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:10:44
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:55:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:55:16
Data point term sent to Coder	System	20 Aug 2020 17:23:57
User entered 'CIPROFLOX (rash)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:38

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

[Condition](#)

Audit	User	Time (GMT)
User entered 'Ciproflox'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'un UNK 2015'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'Jan 2015'	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '2015'	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered empty.	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '9:40'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '20 Aug 2020 9:40'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '161.6' cm	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '78.5' kg	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
Amendment Manager: User entered '30.05986'	System	17 Sep 2020 00:15:37
User entered '30.1'	System	20 Aug 2020 17:12:06
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'kg/m2'	System	20 Aug 2020 17:12:06
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:37:01
Query 'Data is required. Please provide.' answered with 'N/A' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:13
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 17:12:06
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'bpm'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'breaths/min'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'mmHg'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'mmHg'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43

US3432208

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:24

US3432208

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:24

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '1'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'VISIT1'	System	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:05:01

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:48:16
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:48:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 14:05:01
User entered '144051' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:05:01

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:05:01

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

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 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

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 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:41:29

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Pre-Dose (PREDOSE)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '9:40'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '20 Aug 2020 9:40'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '36.4' C	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '53'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'bpm'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '14'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'breaths/min'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '140'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '79'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Post-Dose (POSTDOSE)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:37:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vitals can be assessed 30 minutes following dosage' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:15:13
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 17:14:50
User entered '12:16'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '20 Aug 2020 12:16'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '36.3' C	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '51'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'bpm'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '14'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'breaths/min'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '141'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '82'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:38:40

US3432208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 14:38:40

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '11:45'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '20 Aug 2020 11:45'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Left Arm (LEFT ARM)'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'ONCE'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:15:48

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:15:48

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '10:29'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:15:48

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '20 Aug 2020 10:29'	System	20 Aug 2020 17:15:48

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:35:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '10:16'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '20 Aug 2020 10:16'	System	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered empty.	System	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:50

US3432208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	20 Aug 2020 17:16:50

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered 'Yes (Y)'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:25', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered '97.4'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered 'No (N)'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered '20 Aug 2020 12:22'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 14:35'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:25:39', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered 'Yes (Y)'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:25:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered '97.7'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:25:55', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered 'No (N)'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered '20 Aug 2020 17:26'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 15:30'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 2'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered 'Yes (Y)'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered '98.8'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered 'No (N)'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered '21 Aug 2020 12:12'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 3'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered 'Yes (Y)'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered '96.9'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered 'No (N)'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered '23 Aug 2020 08:18'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 4'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered 'Yes (Y)'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered '98.5'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered 'No (N)'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered '24 Aug 2020 11:11'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 5'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered 'Yes (Y)'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered '97.7'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered 'No (N)'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered '25 Aug 2020 07:59'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 6'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:50:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered 'Yes (Y)'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:50:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered '97.8'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:50:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered 'No (N)'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered '26 Aug 2020 07:51'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 7'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:33:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01' User entered 'Yes (Y)'	System	27 Aug 2020 11:34:11
	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01' User entered '97.4'	System	27 Aug 2020 11:34:11
	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01'	System	27 Aug 2020 11:34:11
User entered 'No (N)'	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01' User entered '27 Aug 2020 07:34'	System	27 Aug 2020 11:34:11
	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'None (1)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'No (N)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'No (N)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'None (1)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered '20 Aug 2020 12:23'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 14:35'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'None (1)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'No (N)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'No (N)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:39', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'None (1)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:42', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered '20 Aug 2020 17:26'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 15:30'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 2'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'None (1)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'No (N)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:28', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'No (N)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'None (1)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered '21 Aug 2020 12:13'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 3'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'None (1)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'No (N)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'No (N)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'None (1)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered '23 Aug 2020 08:19'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 4'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'None (1)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'No (N)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:48', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'No (N)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'None (1)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e' User entered '24 Aug 2020 11:11'	System	24 Aug 2020 15:11:56
	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 5'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'None (1)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'No (N)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'No (N)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'None (1)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered '25 Aug 2020 07:59'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 6'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'None (1)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'No (N)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'No (N)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'None (1)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered '26 Aug 2020 07:51'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 7'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'None (1)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'No (N)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'No (N)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:21', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'None (1)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b' User entered '27 Aug 2020 07:34'	System	27 Aug 2020 11:34:28
	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'No (N)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered '20 Aug 2020 12:24'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 14:35'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:52', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:55', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:27:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:27:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:27:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'No (N)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:27:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468' User entered '20 Aug 2020 17:27'	System	20 Aug 2020 21:27:17
	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Aug 2020 15:30'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 2'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'No (N)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered '21 Aug 2020 12:14'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 3'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'No (N)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered '23 Aug 2020 08:19'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 4'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'No (N)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014' User entered '24 Aug 2020 11:12'	System	24 Aug 2020 15:12:24
	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 5'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:04', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'No (N)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered '25 Aug 2020 08:00'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 6'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:26', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:31', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'No (N)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered '26 Aug 2020 07:51'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 7'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:28', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:32', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:43', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'No (N)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered '27 Aug 2020 07:34'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:35

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '27 Aug 2020'	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:35

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:35

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:35

US3432208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:39

US3432208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'I'	System	27 Aug 2020 18:24:39

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '03 Sep 2020' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	10 Nov 2020 15:09:52
User entered '3 Sep 2020'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:39

US3432208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	03 Sep 2020 19:14:39

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	17 Sep 2020 13:58:54

US3432208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	17 Sep 2020 13:58:54

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Sep 2020'	Jessica Cauley (b) (4)	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Clinic (Clinic)'	Jessica Cauley (b) (4)	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'VISIT2'	System	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '8:26'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '17 Sep 2020 8:26'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '36.8' C	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '71'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'bpm'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '12'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'breaths/min'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '138'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '91'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '10:19'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '17 Sep 2020 10:19'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '37.0' C	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '73'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'bpm'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '20'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'breaths/min'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '138'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '93'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:03:04

US3432208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:03:04

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Jessica Cauley (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Jessica Cauley (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Sep 2020'	Jessica Cauley (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '09:49'	Jessica Cauley (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '17 Sep 2020 09:49'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Left Arm (LEFT ARM)'	Jessica Cauley (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'ONCE'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Sep 2020'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '09:30'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '17 Sep 2020 09:30'	System	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '17 Sep 2020'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '09:35'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '17 Sep 2020 09:35'	System	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'No (N)'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Jessica Cauley (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered empty.	System	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:03:21

US3432208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	17 Sep 2020 17:03:21

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered 'Yes (Y)'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered '98.6'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered 'No (N)'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered '17 Sep 2020 10:26'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 10:09'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered 'Yes (Y)'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered '97.5'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:50', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered 'No (N)'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered '18 Sep 2020 09:50'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 2'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered 'Yes (Y)'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered '97.6'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered 'No (N)'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered '19 Sep 2020 11:21'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 3'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered 'Yes (Y)'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered '97.5'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered 'No (N)'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered '20 Sep 2020 08:32'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 4'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered 'Yes (Y)'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered '97.6'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered 'No (N)'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered '20 Sep 2020 22:36'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 5'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered 'Yes (Y)'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:32', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered '98.2'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered 'No (N)'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:39', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered '21 Sep 2020 13:17'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 6'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d'	System	23 Sep 2020 12:05:31
User entered 'Yes (Y)'	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d' User entered '97.2'	System	23 Sep 2020 12:05:31
	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d'	System	23 Sep 2020 12:05:31
User entered 'No (N)'	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d'	System	23 Sep 2020 12:05:31
User entered '23 Sep 2020 08:05'	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 7'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered 'Yes (Y)'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered '98.1'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered 'No (N)'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered '24 Sep 2020 10:22'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'None (1)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:48', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'No (N)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'No (N)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'None (1)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered '17 Sep 2020 10:26'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 10:09'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'None (1)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'No (N)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'No (N)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'None (1)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered '18 Sep 2020 09:51'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 2'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'None (1)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'No (N)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:48', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'No (N)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'None (1)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered '19 Sep 2020 11:21'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 3'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'None (1)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'No (N)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:42', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'No (N)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'None (1)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered '20 Sep 2020 08:32'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 4'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'None (1)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'No (N)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'No (N)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'None (1)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered '20 Sep 2020 22:37'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 5'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'None (1)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:50', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'No (N)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'No (N)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'None (1)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered '21 Sep 2020 13:17'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 6'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:31', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'None (1)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'No (N)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'No (N)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'None (1)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered '23 Sep 2020 08:05'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 7'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f'	System	24 Sep 2020 14:22:53
User entered 'None (1)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcdc6f'	System	24 Sep 2020 14:22:53
User entered 'No (N)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:43', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f'	System	24 Sep 2020 14:22:53
User entered 'No (N)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f'	System	24 Sep 2020 14:22:53
User entered 'None (1)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f' User entered '24 Sep 2020 10:22'	System	24 Sep 2020 14:22:53
	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'No (N)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:22', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered '17 Sep 2020 10:27'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 10:09'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'No (N)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered '18 Sep 2020 09:51'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 2'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:22', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:26', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'No (N)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:32', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered '19 Sep 2020 11:22'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 3'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:33:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:33:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'No (N)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:33:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered '20 Sep 2020 08:33'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 4'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:21', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:25', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:28', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'No (N)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered '20 Sep 2020 22:37'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 5'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'No (N)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:22', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered '21 Sep 2020 13:18'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 6'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:50', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'No (N)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered '23 Sep 2020 08:05'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 7'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

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 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'No (N)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered '24 Sep 2020 10:23'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:13:04

US3432208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	01 Oct 2020 15:13:04

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:13:30

US3432208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	01 Oct 2020 15:13:30

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 13:20:44

US3432208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	08 Oct 2020 13:20:44

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User entered 'VISIT3'	System	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 15:17:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Oct 2020 15:17:09
User entered '8:22' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:17:09
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 15:16:59
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User entered '13 Oct 2020 8:22'	System	13 Oct 2020 15:17:09
User entered empty.	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '98.4' F	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '97'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User entered 'bpm'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '14'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User entered 'breaths/min'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '139'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User entered 'mmHg'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '88'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49
User entered 'mmHg'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:49

US3432208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:17:18

US3432208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 15:17:18

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '8:56'	(b) (4), (b) (6)	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '13 Oct 2020 8:56'	System	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:17:26

US3432208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	13 Oct 2020 15:17:26

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 64'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 71'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-10-29T06:54:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3e186ded-79d8-415e-9a9e-217a153b0c23'	System	29 Oct 2020 10:55:09
User entered 'No (N)'	System	29 Oct 2020 10:55:09

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-10-29T06:54:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3e186ded-79d8-415e-9a9e-217a153b0c23'	System	29 Oct 2020 10:55:09
User entered 'No (N)'	System	29 Oct 2020 10:55:09

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-10-29T06:55:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3e186ded-79d8-415e-9a9e-217a153b0c23' User entered '29 Oct 2020 06:55:05'	System	29 Oct 2020 10:55:09
	System	29 Oct 2020 10:55:09

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 78'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-11-03T00:02:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'eafb57e0-8029-4142-97b6-e0083cb6eb81'	System	03 Nov 2020 05:02:17
User entered 'No (N)'	System	03 Nov 2020 05:02:17

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-11-03T00:02:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'eafb57e0-8029-4142-97b6-e0083cb6eb81'	System	03 Nov 2020 05:02:17
User entered 'No (N)'	System	03 Nov 2020 05:02:17

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-11-03T00:02:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'eafb57e0-8029-4142-97b6-e0083cb6eb81'	System	03 Nov 2020 05:02:17
User entered '03 Nov 2020 00:02:15'	System	03 Nov 2020 05:02:17

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:55:56
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 92'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:09:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:34:34
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2020-11-24T13:18:55', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e3014c75-8f0a-4339-9fa0-b08ab359f604'	System	24 Nov 2020 18:19:12
User entered 'No (N)'	System	24 Nov 2020 18:19:12

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2020-11-24T13:19:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e3014c75-8f0a-4339-9fa0-b08ab359f604'	System	24 Nov 2020 18:19:12
User entered 'No (N)'	System	24 Nov 2020 18:19:12

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2020-11-24T13:19:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e3014c75-8f0a-4339-9fa0-b08ab359f604'	System	24 Nov 2020 18:19:12
User entered '24 Nov 2020 13:19:07'	System	24 Nov 2020 18:19:12

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2020-12-08T12:53:25', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '08751270-eac8-4933-8cc7-a98c19a67fb2'	System	08 Dec 2020 17:53:51
User entered 'No (N)'	System	08 Dec 2020 17:53:51

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2020-12-08T12:53:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '08751270-eac8-4933-8cc7-a98c19a67fb2'	System	08 Dec 2020 17:53:51
User entered 'No (N)'	System	08 Dec 2020 17:53:51

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2020-12-08T12:53:43', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '08751270-eac8-4933-8cc7-a98c19a67fb2'	System	08 Dec 2020 17:53:51
User entered '08 Dec 2020 12:53:43'	System	08 Dec 2020 17:53:51

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2020-12-14T17:20:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a79be996-a9f7-4335-a8b9-95beb7cc8b18'	System	14 Dec 2020 22:21:20
User entered 'No (N)'	System	14 Dec 2020 22:21:20

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2020-12-14T17:21:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a79be996-a9f7-4335-a8b9-95beb7cc8b18'	System	14 Dec 2020 22:21:20
User entered 'No (N)'	System	14 Dec 2020 22:21:20

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2020-12-14T17:21:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a79be996-a9f7-4335-a8b9-95beb7cc8b18'	System	14 Dec 2020 22:21:20
User entered '14 Dec 2020 17:21:15'	System	14 Dec 2020 22:21:20

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2020-12-19T03:24:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '04b9b287-f838-4e45-9e11-2af42f3c6b28'	System	19 Dec 2020 08:24:27
User entered 'No (N)'	System	19 Dec 2020 08:24:27

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2020-12-19T03:24:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '04b9b287-f838-4e45-9e11-2af42f3c6b28'	System	19 Dec 2020 08:24:27
User entered 'No (N)'	System	19 Dec 2020 08:24:27

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2020-12-19T03:24:21', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '04b9b287-f838-4e45-9e11-2af42f3c6b28'	System	19 Dec 2020 08:24:27
User entered '19 Dec 2020 03:24:21'	System	19 Dec 2020 08:24:27

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2020-12-28T12:01:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b5373bf2-fe11-4f24-bf4b-4b469de5dcc5'	System	28 Dec 2020 17:01:29
User entered 'No (N)'	System	28 Dec 2020 17:01:29

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2020-12-28T12:01:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b5373bf2-fe11-4f24-bf4b-4b469de5dcc5'	System	28 Dec 2020 17:01:29
User entered 'No (N)'	System	28 Dec 2020 17:01:29

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2020-12-28T12:01:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b5373bf2-fe11-4f24-bf4b-4b469de5dcc5'	System	28 Dec 2020 17:01:29
User entered '28 Dec 2020 12:01:20'	System	28 Dec 2020 17:01:29

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-01-02T19:14:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9b61b747-5ee5-4eba-a3c5-cae63bbc36bd'	System	03 Jan 2021 00:14:51
User entered 'No (N)'	System	03 Jan 2021 00:14:51

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-01-02T19:14:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9b61b747-5ee5-4eba-a3c5-cae63bbc36bd'	System	03 Jan 2021 00:14:51
User entered 'No (N)'	System	03 Jan 2021 00:14:51

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-01-02T19:14:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9b61b747-5ee5-4eba-a3c5-cae63bbc36bd'	System	03 Jan 2021 00:14:51
User entered '02 Jan 2021 19:14:44'	System	03 Jan 2021 00:14:51

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-01-09T05:42:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78e292a9-28c6-4960-b824-167d69717506'	System	09 Jan 2021 10:42:30
User entered 'No (N)'	System	09 Jan 2021 10:42:30

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-01-09T05:42:22', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78e292a9-28c6-4960-b824-167d69717506'	System	09 Jan 2021 10:42:30
User entered 'No (N)'	System	09 Jan 2021 10:42:30

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-01-09T05:42:25', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78e292a9-28c6-4960-b824-167d69717506'	System	09 Jan 2021 10:42:30
User entered '09 Jan 2021 05:42:25'	System	09 Jan 2021 10:42:30

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-01-16T08:15:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd70d912a-dbca-4cf9-a9d8-bba992ec4671'	System	16 Jan 2021 13:15:21
User entered 'No (N)'	System	16 Jan 2021 13:15:21

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-01-16T08:15:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd70d912a-dbca-4cf9-a9d8-bba992ec4671'	System	16 Jan 2021 13:15:21
User entered 'No (N)'	System	16 Jan 2021 13:15:21

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-01-16T08:15:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd70d912a-dbca-4cf9-a9d8-bba992ec4671' User entered '16 Jan 2021 08:15:18'	System	16 Jan 2021 13:15:21
	System	16 Jan 2021 13:15:21

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-01-23T01:06:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'dd301782-6825-4056-87f7-25baf2d45b0f'	System	23 Jan 2021 06:07:03
User entered 'No (N)'	System	23 Jan 2021 06:07:03

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-01-23T01:06:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'dd301782-6825-4056-87f7-25baf2d45b0f'	System	23 Jan 2021 06:07:03
User entered 'No (N)'	System	23 Jan 2021 06:07:03

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-01-23T01:06:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'dd301782-6825-4056-87f7-25baf2d45b0f'	System	23 Jan 2021 06:07:03
User entered '23 Jan 2021 01:06:58'	System	23 Jan 2021 06:07:03

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-01-30T07:51:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9c0361de-ed82-4555-9a15-e1c73ca952ba'	System	30 Jan 2021 12:52:02
User entered 'No (N)'	System	30 Jan 2021 12:52:02

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-01-30T07:51:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9c0361de-ed82-4555-9a15-e1c73ca952ba'	System	30 Jan 2021 12:52:02
User entered 'No (N)'	System	30 Jan 2021 12:52:02

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-01-30T07:51:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9c0361de-ed82-4555-9a15-e1c73ca952ba'	System	30 Jan 2021 12:52:02
User entered '30 Jan 2021 07:51:58'	System	30 Jan 2021 12:52:02

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-02-06T20:09:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '699aebcc-7317-42c0-a3fb-f31f0f70aaa3'	System	07 Feb 2021 01:10:13
User entered 'No (N)'	System	07 Feb 2021 01:10:13

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-02-06T20:10:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '699aebcc-7317-42c0-a3fb-f31f0f70aaa3'	System	07 Feb 2021 01:10:13
User entered 'No (N)'	System	07 Feb 2021 01:10:13

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-02-06T20:10:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '699aebcc-7317-42c0-a3fb-f31f0f70aaa3'	System	07 Feb 2021 01:10:13
User entered '06 Feb 2021 20:10:09'	System	07 Feb 2021 01:10:13

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-02-13T07:40:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b9587637-3530-40c2-8de0-b3160ed2c50d'	System	13 Feb 2021 12:40:56
User entered 'No (N)'	System	13 Feb 2021 12:40:56

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-02-13T07:40:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b9587637-3530-40c2-8de0-b3160ed2c50d'	System	13 Feb 2021 12:40:56
User entered 'No (N)'	System	13 Feb 2021 12:40:56

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-02-13T07:40:52', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b9587637-3530-40c2-8de0-b3160ed2c50d'	System	13 Feb 2021 12:40:56
User entered '13 Feb 2021 07:40:52'	System	13 Feb 2021 12:40:56

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-02-23T12:05:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce3064cc-2fec-477c-b482-8cd889c92cdc'	System	23 Feb 2021 17:17:26
User entered 'No (N)'	System	23 Feb 2021 17:17:26

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-02-23T12:05:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce3064cc-2fec-477c-b482-8cd889c92cdc'	System	23 Feb 2021 17:17:26
User entered 'No (N)'	System	23 Feb 2021 17:17:26

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-02-23T12:05:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce3064cc-2fec-477c-b482-8cd889c92cdc'	System	23 Feb 2021 17:17:26
User entered '23 Feb 2021 12:05:11'	System	23 Feb 2021 17:17:26

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-02-27T01:31:24-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5889872d-49cd-453f-9f99-facc39531316'	System	27 Feb 2021 06:31:31
User entered 'No (N)'	System	27 Feb 2021 06:31:31

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-02-27T01:31:26-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5889872d-49cd-453f-9f99-facc39531316'	System	27 Feb 2021 06:31:31
User entered 'No (N)'	System	27 Feb 2021 06:31:31

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-02-27T01:31:28-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5889872d-49cd-453f-9f99-facc39531316'	System	27 Feb 2021 06:31:31
User entered '27 Feb 2021 01:31:28'	System	27 Feb 2021 06:31:31

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-03-06T00:02:51-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7d065929-10db-4be8-8dcb-9a4ef57d8768'	System	06 Mar 2021 05:05:18
User entered 'No (N)'	System	06 Mar 2021 05:05:18

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-03-06T00:02:53-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7d065929-10db-4be8-8dcb-9a4ef57d8768'	System	06 Mar 2021 05:05:18
User entered 'No (N)'	System	06 Mar 2021 05:05:18

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-03-06T00:02:57-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7d065929-10db-4be8-8dcb-9a4ef57d8768' User entered '06 Mar 2021 00:02:57'	System	06 Mar 2021 05:05:18
	System	06 Mar 2021 05:05:18

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-03-13T00:29:52-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '13c12455-bdfe-4800-997e-06f610aeb293'	System	13 Mar 2021 05:31:04
User entered 'No (N)'	System	13 Mar 2021 05:31:04

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-03-13T00:29:54-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '13c12455-bdfe-4800-997e-06f610aeb293'	System	13 Mar 2021 05:31:04
User entered 'No (N)'	System	13 Mar 2021 05:31:04

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-03-13T00:29:57-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '13c12455-bdfe-4800-997e-06f610aeb293'	System	13 Mar 2021 05:31:04
User entered '13 Mar 2021 00:29:57'	System	13 Mar 2021 05:31:04

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-03-20T00:01:34-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '870c2657-66f0-4f68-a593-7ed1aa582892'	System	20 Mar 2021 04:03:30
User entered 'No (N)'	System	20 Mar 2021 04:03:30

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-03-20T00:01:38-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '870c2657-66f0-4f68-a593-7ed1aa582892'	System	20 Mar 2021 04:03:30
User entered 'No (N)'	System	20 Mar 2021 04:03:30

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-03-20T00:01:41-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '870c2657-66f0-4f68-a593-7ed1aa582892' User entered '20 Mar 2021 00:01:41'	System	20 Mar 2021 04:03:30
	System	20 Mar 2021 04:03:30

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-03-27T00:14:56-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '325734f9-4492-45b7-abc1-62d3179fbef6'	System	27 Mar 2021 04:18:42
User entered 'No (N)'	System	27 Mar 2021 04:18:42

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-03-27T00:15:14-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '325734f9-4492-45b7-abc1-62d3179fbef6'	System	27 Mar 2021 04:18:42
User entered 'No (N)'	System	27 Mar 2021 04:18:42

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-03-27T00:15:18-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '325734f9-4492-45b7-abc1-62d3179fbef6' User entered '27 Mar 2021 00:15:18'	System	27 Mar 2021 04:18:42
	System	27 Mar 2021 04:18:42

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-04-03T08:51:51-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3b1daeae-fa00-4c8c-906c-b9f7708ff37d'	System	03 Apr 2021 12:52:35
User entered 'No (N)'	System	03 Apr 2021 12:52:35

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-04-03T08:52:26-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3b1daeae-fa00-4c8c-906c-b9f7708ff37d'	System	03 Apr 2021 12:52:35
User entered 'No (N)'	System	03 Apr 2021 12:52:35

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-04-03T08:52:30-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3b1daeae-fa00-4c8c-906c-b9f7708ff37d'	System	03 Apr 2021 12:52:35
User entered '03 Apr 2021 08:52:30'	System	03 Apr 2021 12:52:35

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-04-10T01:10:41-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c93e5439-8eb1-4fde-9bc3-27184081b0c9'	System	10 Apr 2021 05:11:06
User entered 'No (N)'	System	10 Apr 2021 05:11:06

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-04-10T01:10:54-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c93e5439-8eb1-4fde-9bc3-27184081b0c9'	System	10 Apr 2021 05:11:06
User entered 'No (N)'	System	10 Apr 2021 05:11:06

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-04-10T01:11:01-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c93e5439-8eb1-4fde-9bc3-27184081b0c9'	System	10 Apr 2021 05:11:06
User entered '10 Apr 2021 01:11:01'	System	10 Apr 2021 05:11:06

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-04-17T00:23:40-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e0e39856-816b-488b-8602-deaca4080a72'	System	17 Apr 2021 04:23:50
User entered 'No (N)'	System	17 Apr 2021 04:23:50

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-04-17T00:23:42-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e0e39856-816b-488b-8602-deaca4080a72'	System	17 Apr 2021 04:23:50
User entered 'No (N)'	System	17 Apr 2021 04:23:50

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-04-17T00:23:47-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e0e39856-816b-488b-8602-deaca4080a72'	System	17 Apr 2021 04:23:50
User entered '17 Apr 2021 00:23:47'	System	17 Apr 2021 04:23:50

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-04-25T20:30:41-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '22c46eb9-6853-47f8-a0ae-097ccb4c325c'	System	26 Apr 2021 00:30:55
User entered 'No (N)'	System	26 Apr 2021 00:30:55

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-04-25T20:30:46-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '22c46eb9-6853-47f8-a0ae-097ccb4c325c'	System	26 Apr 2021 00:30:55
User entered 'No (N)'	System	26 Apr 2021 00:30:55

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-04-25T20:30:51-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '22c46eb9-6853-47f8-a0ae-097ccb4c325c'	System	26 Apr 2021 00:30:55
User entered '25 Apr 2021 20:30:51'	System	26 Apr 2021 00:30:55

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[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 (4c534fb9ff11f482)', Time: '2021-05-01T14:15:56-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7fda1fb3-1243-401c-a280-7367981c3b2b'	System	01 May 2021 18:16:06
User entered 'No (N)'	System	01 May 2021 18:16:06

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

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 (4c534fb9ff11f482)', Time: '2021-05-01T14:15:59-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7fda1fb3-1243-401c-a280-7367981c3b2b'	System	01 May 2021 18:16:06
User entered 'No (N)'	System	01 May 2021 18:16:06

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-05-01T14:16:01-04:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7fda1fb3-1243-401c-a280-7367981c3b2b' User entered '01 May 2021 14:16:01'	System	01 May 2021 18:16:06
	System	01 May 2021 18:16:06

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:35:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
User opened query ' Per CDM RQ: Response noted. Please keep query open until update has been made. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:33:53
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:33:53
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'please see my answer to all the rest of these. please stop putting queries for these.' (Site from DM).	Monica Feeley (b) (4) (b) (4)	24 Mar 2021 15:36:02
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 00:38:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-03-02T18:13:37-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6e1f8fb8-290b-4b22-9e86-909cc9ee5cf4'	System	02 Mar 2021 23:16:21
User entered 'Yes (Y)'	System	02 Mar 2021 23:16:21

US3432208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:35:02

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-03-02T18:13:41-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6e1f8fb8-290b-4b22-9e86-909cc9ee5cf4'	System	02 Mar 2021 23:16:21
User entered 'Yes (Y)'	System	02 Mar 2021 23:16:21

US3432208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:35:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2021-03-02T18:13:44-05:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6e1f8fb8-290b-4b22-9e86-909cc9ee5cf4'	System	02 Mar 2021 23:16:21
User entered '02 Mar 2021 18:13:44'	System	02 Mar 2021 23:16:21

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '12 Nov 2020'	Kathleen Garvey (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	Kathleen Garvey (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	12 Nov 2020 17:20:46

US3432208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:08:03
User entered '1'	System	12 Nov 2020 17:20:46

US3432208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	14 Dec 2020 22:24:37

US3432208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '14 Dec 2020'	Kathleen Garvey (b) (4)	14 Dec 2020 22:24:37

US3432208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	14 Dec 2020 22:24:37

US3432208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Kathleen Garvey (b) (4)	14 Dec 2020 22:24:37

US3432208

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	14 Dec 2020 22:24:42

US3432208

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User entered 'I'	System	14 Dec 2020 22:24:42

US3432208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 18:23:23

US3432208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '13 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 18:23:23

US3432208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 18:23:23

US3432208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 18:23:23

US3432208

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 18:23:29

US3432208

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User entered '1'	System	13 Jan 2021 18:23:29

US3432208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	12 Feb 2021 18:15:51

US3432208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '12 Feb 2021'	Tenaizus Woods (b) (4)	12 Feb 2021 18:15:51

US3432208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	12 Feb 2021 18:15:51

US3432208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Tenaizus Woods (b) (4)	12 Feb 2021 18:15:51

US3432208

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	12 Feb 2021 18:15:54

US3432208

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:27:10
User entered '1'	System	12 Feb 2021 18:15:54

US3432208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:09:50

US3432208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Mar 2021' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:47
User entered '29 Mar 2021'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:09:50

US3432208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:09:50

US3432208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'VISIT4'	System	29 Mar 2021 13:09:50

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 13:10:47
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	29 Mar 2021 13:10:47
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 13:10:38
User entered '26 Mar 2021'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '7:27'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '26 Mar 2021 7:27'	System	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '36.9' C	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '71'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'bpm'	System	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '12'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'breaths/min'	System	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '130'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'mmHg'	System	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '82'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered 'mmHg'	System	29 Mar 2021 13:10:38

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43

US3432208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43

US3432208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'No (N)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:11:07

US3432208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Phoebe Cunningham (b) (4)	29 Mar 2021 13:11:07

US3432208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:11:02

US3432208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Mar 2021'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:11:02

US3432208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '7:29'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:11:02

US3432208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '26 Mar 2021 7:29'	System	29 Mar 2021 13:11:02

US3432208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:11:12

US3432208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:43
User entered '1'	System	29 Mar 2021 13:11:12

US3432208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	12 Apr 2021 15:01:58

US3432208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '12 Apr 2021'	(b) (4), (b) (6) [REDACTED]	12 Apr 2021 15:01:58

US3432208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) [REDACTED]	12 Apr 2021 15:01:58

US3432208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	(b) (4), (b) (6) [REDACTED]	12 Apr 2021 15:01:58

US3432208

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	12 Apr 2021 15:02:03

US3432208

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 15:02:03

US3432208

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:32

US3432208

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:32

US3432208

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:32

US3432208

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 16:17:32

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	Bruce Bausk (b) (4)	09 Mar 2021 19:56:46
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:57:01

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	Bruce Bausk (b) (4)	09 Mar 2021 19:56:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:57:01

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Placebo (Placebo)'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Placebo (Placebo)'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Placebo (Placebo)'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '1'	System	25 Jan 2021 16:17:50

US3432208

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:02

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '1'	System	25 Jan 2021 16:17:50

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered empty.	System	25 Jan 2021 16:19:38
DataPoint set to visible.	System	25 Jan 2021 16:17:50

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered empty.	System	25 Jan 2021 16:19:38
DataPoint set to visible.	System	25 Jan 2021 16:17:50

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '07:22'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '25 Jan 2021 07:22'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '36.8' C	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '67'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'bpm'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '14'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'breaths/min'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '135'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '86'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered empty.	System	25 Jan 2021 16:19:38
DataPoint set to visible.	System	25 Jan 2021 16:17:50

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '08:51'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '25 Jan 2021 08:51'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '98.5' F	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '69'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'bpm'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '14'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'breaths/min'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '129'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '84'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:38

US3432208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	25 Jan 2021 16:19:38

US3432208

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:51

US3432208

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:19:51

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Julia Klopfer (b) (4)	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered empty.	Julia Klopfer (b) (4)	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mRNA-1273'	System	25 Jan 2021 16:20:12
DataPoint set to visible.	System	25 Jan 2021 16:17:50

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '08:21'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '25 Jan 2021 08:21'	System	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Left Arm (LEFT ARM)'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'ONCE'	System	25 Jan 2021 16:20:12

US3432208

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

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 16:20:12

US3432208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:33

US3432208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'Per Preclarus, received by PPD on 03Feb2021 Accession Number: 1F608YC' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 09:14:57
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '25 Jan 2021'	Bruce Bausk (b) (4) (b) (4)	09 Mar 2021 19:57:43
	(b) (4), (b) (6)	08 Feb 2021 17:04:19
	Julia Klopfer (b) (4) (b) (4)	25 Jan 2021 16:20:33

US3432208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '07:28'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:33

US3432208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '25 Jan 2021 07:28'	System	25 Jan 2021 16:20:33

US3432208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:52

US3432208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '25 Jan 2021'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:52

US3432208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '07:33'	Julia Klopfer (b) (4)	25 Jan 2021 16:20:52

US3432208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '25 Jan 2021 07:33'	System	25 Jan 2021 16:20:52

US3432208

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

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	25 Jan 2021 16:21:09

US3432208

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

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '1'	System	25 Jan 2021 16:21:09

US3432208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 14:22:20

US3432208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered '1 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 14:22:20

US3432208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 14:22:20

US3432208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 14:22:20

US3432208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 14:23:56

US3432208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '1'	System	01 Feb 2021 14:23:56

US3432208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '1'	System	01 Feb 2021 14:23:56
DataPoint set to visible.	System	01 Feb 2021 14:23:56

US3432208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	26 Feb 2021 23:47:03

US3432208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Feb 2021'	Jessica Cauley (b) (4)	26 Feb 2021 23:47:03

US3432208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Clinic (Clinic)'	Jessica Cauley (b) (4)	26 Feb 2021 23:47:03

US3432208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'OLD29'	System	26 Feb 2021 23:47:03

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User accepted default value 'Pre-Dose (PREDOSE)'	Jessica Cauley (b) (4) (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Feb 2021'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '16:05'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '26 Feb 2021 16:05'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '98.2' F	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Oral (Oral)'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '085'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'bpm'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '16'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'breaths/min'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '131'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '069'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User accepted default value 'Post-Dose (POSTDOSE)'	Jessica Cauley (b) (4) (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Feb 2021'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '17:06'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '26 Feb 2021 17:06'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '97.8' F	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Oral (Oral)'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '077'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'bpm'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '16'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'breaths/min'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '139'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '086'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	26 Feb 2021 23:49:02

US3432208

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:08

US3432208

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Feb 2021'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:08

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Jessica Cauley (b) (4)	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Jessica Cauley (b) (4)	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mRNA-1273'	System	26 Feb 2021 23:49:24
DataPoint set to visible.	System	01 Feb 2021 14:23:56

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Feb 2021'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '16:30'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '26 Feb 2021 16:30'	System	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Left Arm (LEFT ARM)'	Jessica Cauley (b) (4)	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'ONCE'	System	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 23:49:24

US3432208

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 23:13:48

US3432208

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '1'	System	05 Mar 2021 23:13:48

US3432208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 23:14:09

US3432208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '05 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 23:14:09

US3432208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Mar 2021 23:14:09

US3432208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:14:09

US3432208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 23:14:30

US3432208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'I'	System	05 Mar 2021 23:14:30

US3432208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:03:49

US3432208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Mar 2021'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:03:49

US3432208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:03:49

US3432208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'OLD57'	System	29 Mar 2021 13:03:49

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Mar 2021'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '7:27'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '26 Mar 2021 7:27'	System	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '36.9' C	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '71'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'bpm'	System	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '12'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'breaths/min'	System	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '130'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '82'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered 'mmHg'	System	29 Mar 2021 13:04:29

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47

US3432208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47

US3432208

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'No (N)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:33

US3432208

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:33

US3432208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:46

US3432208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '26 Mar 2021'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:46

US3432208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '7:29'	Phoebe Cunningham (b) (4)	29 Mar 2021 13:04:46

US3432208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:36:47
User entered '26 Mar 2021 7:29'	System	29 Mar 2021 13:04:46

US3432208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:35:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:39:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:20:09

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:16
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:01:51
	[REDACTED]	
User entered 'USA-US078-2020-mRNA-1273-P301000004'	System	14 Oct 2020 12:01:46
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 12:01:46
	[REDACTED]	
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:19
	[REDACTED]	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 14:31:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 14:31:32
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 14:30:42
User entered 'Spinal Stenosis'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:22
	[REDACTED]	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:07
	[REDACTED]	
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:08
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:08:01
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'this was entered incorrectly' (Site from Safety).	Monica Feeley (b) (4)	15 Oct 2020 15:46:25
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	15 Oct 2020 15:46:12
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 12:00:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:10
	[REDACTED]	
User entered '07 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:12
	[REDACTED]	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:14
	[REDACTED]	
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:16
	[REDACTED]	
User entered '05 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:17
	[REDACTED]	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	(b) (4), (b) (6)	
User closed query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider updating to grade 4.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 00:19:29
Query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider updating to grade 4.' answered with 'grade for is life threatening, of which, this was not' (Site from Safety).	Monica Feeley (b) (4)	20 Nov 2020 19:46:16
	(b) (4)	
User opened query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider updating to grade 4.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:59:22
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:22
	[REDACTED]	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:25
	[REDACTED]	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:28
	[REDACTED]	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:30
	[REDACTED]	
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:31
	[REDACTED]	
User entered '02 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:34
	[REDACTED]	
User entered '05 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:35
	[REDACTED]	
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:38
	[REDACTED]	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:39
	[REDACTED]	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:41
	[REDACTED]	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:43
	[REDACTED]	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:44
	[REDACTED]	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:57:18
	[REDACTED]	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	(b) (4), (b) (6)	29 Oct 2020 20:50:44
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If dose is delayed, please update action to Dose delayed. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	Monica Feeley (b) (4)	28 Oct 2020 16:14:19
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If dose is delayed, please update action to Dose delayed. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'There was no action taken. received both first and second dose within window' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:57:23
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:28:39
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If dose is delayed, please update action to Dose delayed. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 14:30:36
User entered 'None (NONE)'	(b) (4), (b) (6)	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:31:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User closed query 'Per DM CLR: Other Action Taken = None. However, it appears that the subject had a Cervical Discectomy + Fusion as treatment for this AE. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = None. However, it appears that the subject had a Cervical Discectomy + Fusion as treatment for this AE. Please review and update applicable details accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:55:46
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 14:14:04
User entered '0' reason for change: Per Query Resolution	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
User opened query 'Per DM CLR: Other Action Taken = None. However, it appears that the subject had a Cervical Discectomy + Fusion as treatment for this AE. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:13:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:40:35
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 14:58:03
	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:31:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
User entered '1' reason for change: New Information	(b) (4) Monica Feeley (b) (4)	30 Oct 2020 14:13:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:58:04
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:06
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
User entered '1' reason for change: New Information	(b) (4)	
	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 14:58:06
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:09
	[REDACTED]	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:10
	[REDACTED]	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36
	[REDACTED]	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:14
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 19:48:34
User entered 'AN MRI OF C-SPINE ON 9/7/2020 REVEALED CANAL STENOSIS AT C5-7; HE UNDERWENT AN ANTERIOR CERVICAL DISECTOMY + FUSION ON 10/2/2020; POST OP COURSE UNREMARKABLE AND DISCHARGED ON 10/5/2020. Participant reported this to site on 13OCT2020 during their scheduled visit 3.' reason for change: Per Query Resolution	Monica Feeley (b) (4)	20 Nov 2020 19:48:34
User closed query 'PV Query: Please provide treatment medications given for the event. 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).	(b) (4), (b) (6)	11 Nov 2020 17:58:32
Query 'PV Query: Please provide treatment medications given for the event. 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.' answered with 'see con med' (Site from Safety).	Monica Feeley (b) (4)	10 Nov 2020 21:43:42
User opened query 'PV Query: Please provide treatment medications given for the event. 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).	(b) (4), (b) (6)	06 Nov 2020 12:39:06

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE narrative indicates that the subject underwent MRI of Cervical spine and had Cervical Discectomy + Fusion. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:55:24
User closed query 'PV Query: Please provide treatment medications given for the event. 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).	(b) (4), (b) (6)	02 Nov 2020 13:52:45
Query 'Per DM CLR: SAE narrative indicates that the subject underwent MRI of Cervical spine and had Cervical Discectomy + Fusion. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'please see con procedures updates' (Site from DM).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 14:27:18
Query 'PV Query: Please provide treatment medications given for the event. 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.' answered with 'please see con medications for updated' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 14:26:58
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:50:11
User opened query 'Per DM CLR: SAE narrative indicates that the subject underwent MRI of Cervical spine and had Cervical Discectomy + Fusion. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:41:01

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '05OCT2020 COVID-19 test negative' (Site from Safety). DataPoint Verified.	Monica Feeley (b) (4) (b) (4)	28 Oct 2020 16:19:51
	(b) (4), (b) (6)	23 Oct 2020 14:58:15
User opened query 'PV Query: Please provide treatment medications given for the event. 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).	(b) (4), (b) (6)	23 Oct 2020 14:28:26
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)	23 Oct 2020 14:28:12
User entered 'An MRI of c-Spine on 9/7/2020 revealed canal stenosis at C5-7; he underwent an anterior cervical disectomy + fusion on 10/2/2020; post op course unremarkable and discharged on 10/5/2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Neurological and psychiatric procedural complications, PT: Procedural anxiety, LLT: Procedural anxiety - version MedDRA\23.0.	Coder Import (b) (4)	08 Mar 2021 10:54:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Mar 2021 10:54:02
Data point term sent to Coder	System	05 Mar 2021 23:35:28
User entered 'ANXIETY RELATED TO SPINAL STENOSIS PROCEDURE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:35:25
User entered 'Anxiety prior to spinal stenosis procedure'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User entered empty.	System	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '06 Oct 2020'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User entered empty.	System	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '1'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:40:45
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User entered '0'	System	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17
User entered '1'	System	05 Mar 2021 23:34:49

US3432208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:17

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:35:02

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

Audit	User	Time (GMT)
User opened query 'Per CDM RQ: Response noted. Please keep query open until update has been made. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:39:37
User closed query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:39:37
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' answered with 'we have to follow up with participant. moderna did not send out guidance regarding capturing these until a while after. we are trying to catch up on everyone. please hold off on adding queries regarding these.' (Site from DM).	Monica Feeley (b) (4) (b) (4)	19 Mar 2021 14:16:53
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:39:35
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User closed query 'Per ETRTR: Please confirm SAE "Spinal Stenosis" did not required ConMed, otherwise update accordingly, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:47:23
Query 'Per ETRTR: Please confirm SAE "Spinal Stenosis" did not required ConMed, otherwise update accordingly, thanks.' answered with 'Updated' (Site from CRA).	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:15:28
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:35:14
User opened query 'Per ETRTR: Please confirm SAE "Spinal Stenosis" did not required ConMed, otherwise update accordingly, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 21:59:03
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:24:00

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:26:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:26:31
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 17:26:04
User entered 'Norvasc'	Phoebe Cunningham	20 Aug 2020 17:25:59
	(b) (4)	
	[REDACTED]	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Hypertension'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '10'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'mg (mg)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'once daily (QD)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:25:59
User entered 'un UNK 2000'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
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)	20 Aug 2020 17:28:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:28:24
Data point term sent to Coder	System	20 Aug 2020 17:27:05
User entered 'Metformin'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42
	[REDACTED]	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Type II Diabetes'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '500'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'mg (mg)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'twice daily (BID)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:26:42
User entered 'un UNK 2018'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:30:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:30:31
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 17:29:15
User entered 'Sertraline'	Phoebe Cunningham	20 Aug 2020 17:28:52
	(b) (4)	
	[REDACTED]	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Depression'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per DM CLR-RQ: Response noted. However, please re-confirm it the recorded dose is correct and update dose as appropriate (eg, 25mg, 50 mg, 100 mg, etc). Else, provide re-clarification or re-confirmation on dose. ' (Site from DM). Query 'Per DM CLR-RQ: Response noted. However, please re-confirm it the recorded dose is correct and update dose as appropriate (eg, 25mg, 50 mg, 100 mg, etc). Else, provide re-clarification or re-confirmation on dose. ' answered with 'pt confirmed dosage is 10mg' (Site from DM).	(b) (4), (b) (6) Kathleen Garvey (b) (4) (b) (4)	15 Dec 2020 04:48:05 14 Dec 2020 22:21:44
User opened query 'Per DM CLR-RQ: Response noted. However, please re-confirm it the recorded dose is correct and update dose as appropriate (eg, 25mg, 50 mg, 100 mg, etc). Else, provide re-clarification or re-confirmation on dose. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 04:18:22
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:41:14
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' ' answered with 'Dose is reported as reported by participant' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:12:21
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:03:56
User entered '10'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'mg (mg)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'once daily (QD)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:28:52
User entered 'un UNK 2015'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:32:25
	[REDACTED]	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:32:25
	[REDACTED]	
Data point term sent to Coder User entered 'Omeprazole'	System Phoebe Cunningham (b) (4)	20 Aug 2020 17:31:24 20 Aug 2020 17:30:25
	[REDACTED]	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Dyspepsia'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '40'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'mg (mg)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'other (OTHER)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'twice a day and as needed'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:30:25
User entered 'un UNK 2017'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 21:51:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 21:51:46
Data point term sent to Coder	System	10 Nov 2020 21:51:26
User entered 'Lorazepam'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:24
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 21:29:19
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 23:23:02
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:33:35
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:22
User entered 'Anxiety'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:26
User entered '0.5'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:28
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:30
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:32
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:34
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:44
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:47
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:49
User entered '5 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:51
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:54
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:59
User entered '6 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:02
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User entered empty.	System	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User entered empty.	System	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:05
User entered empty.	System	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:51:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:51:51
Data point term sent to Coder	System	10 Nov 2020 21:58:42
User entered 'Hydromorphone'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:53
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:55
User entered 'Pain from spine surgery'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:38
Query 'Hydromorphone: EMR: 0.2-0.4mg: IV: 03-04Oct20, please add new entry, since dates are different' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:48:15
Query 'Per source EMR: dose is 0.5mg only on 2Oct20, please review and edit. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:48:07
User opened query 'Hydromorphone: EMR: 0.2-0.4mg: IV: 03-04Oct20, please add new entry, since dates are different' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:45:05
User opened query 'Per source EMR: dose is 0.5mg only on 2Oct20, please review and edit. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:41:50
User entered '0.2-0.5'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:59
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:40
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:41
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:43
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:45
User entered 'Intravenous (INTRAVENOUS)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:47
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:50:47
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:50:49
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:50:51
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'per EMR: 0.2-0.5mg: was given till 4Oct20.. please update stop date. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:54:32
Query 'per EMR: 0.2-0.5mg: was given till 4Oct20.. please update stop date. ' answered with 'per safety call OL 36, participant reported stopping medication on 02OCT2020, before the 04OCT2020 stop date.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 23:33:04
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:53:06
User opened query 'per EMR: 0.2-0.5mg: was given till 4Oct20.. please update stop date. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 20:53:02
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:53:04
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User entered empty.	System	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User entered empty.	System	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:08
User entered empty.	System	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:54:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:54:55
Data point term sent to Coder	System	10 Nov 2020 21:58:43
Data point term sent to Coder	System	10 Nov 2020 21:54:31
User entered 'Hydromorphone'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:37
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:39
User entered 'Pain from spine surgery'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:41
User entered '2-4' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered '0.2-0.5'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:44
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:49
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:50
User entered 'other (OTHER)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:03
User entered 'Every 3 hours' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:21
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered 'Intravenous (INTRAVENOUS)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:25
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:29
User entered '4 Oct 2020' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:32
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:34
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:38
User entered '6 Oct 2020' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:40
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User entered empty.	System	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User entered empty.	System	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:14
User entered empty.	System	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:01:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:01:32
Data point term sent to Coder	System	10 Nov 2020 22:00:47
User entered 'Oxycodone'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:19
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:21
User entered 'Pain from spine surgery'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:25
User entered '5-10'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:29
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:44
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:50
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:03
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:07
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:11
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:25
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:27
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:30
User entered '4 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:32
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User entered empty.	System	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User entered empty.	System	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:18
User entered empty.	System	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:00:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:00:40
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Mar 2021 23:28:24 05 Mar 2021 23:28:08
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:17:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:17:42
Data point term sent to Coder User entered 'Zofran'	System Alexander Mills (b) (4)	10 Nov 2020 22:01:49 10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:40
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:05:36
User closed query 'Per DM CLR: Please note that there is no AE that matches Con Med # 09 and # 10 indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 21:29:51
Query 'Per DM CLR: Please note that there is no AE that matches Con Med # 09 and # 10 indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Indication updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 23:28:28
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 23:28:08
User entered 'Con Medication related to procedure for AE #1 Spinal stenosis' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 23:28:08
User opened query 'Per DM CLR: Please note that there is no AE that matches Con Med # 09 and # 10 indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:34:08
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:45
User entered 'Nausea'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:49
User entered '4'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:44
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:01:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:01:48
User entered 'mg (mg)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:01:48
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:01:33
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:49
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:38:57
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'taken every 6 hours is not an option ' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:03:57
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:05:32
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:52
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:56
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:59
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:05
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:09
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:14
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:32:46
User closed query 'Source EMR: stop date is 06Oct20, please review and edit' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:32:44
Query 'Source EMR: stop date is 06Oct20, please review and edit' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:04:18
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:04:14
User opened query 'Source EMR: stop date is 06Oct20, please review and edit' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:00:56
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:18
User entered 'Yes (Y)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:32:47
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 20:04:14
User entered '06 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:04:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:21
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:25
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User entered empty.	System	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User entered empty.	System	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:32
User entered empty.	System	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:19:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:19:41
Data point term sent to Coder	System	10 Nov 2020 22:03:56
User entered 'Zofran'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:35
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:38
User entered 'Nausea'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 11:24:56
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Participant reported taking this dosage' (Site from DM).	Alexander Mills (b) (4)	27 Jan 2021 18:17:30
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:34:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:40
User entered '2'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:42
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:03:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:03:22
User entered 'mg (mg)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:03:22
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:03:12
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:44
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:02:44
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'this is every 6 hours?' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:04:38
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:48
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:50
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:53
User entered 'Intravenous (INTRAVENOUS)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:56
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:58
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:00
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:03
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:15:51
User closed query 'Per AE record subject was discharged 5-Oct-20. Did they administer IV Zofran at home?' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:15:50
Query 'Per AE record subject was discharged 5-Oct-20. Did they administer IV Zofran at home?' answered with 'pt confirmed they did not administer zofran at home, only was given when in hospital' (Site from CRA).	Kathleen Garvey (b) (4)	14 Dec 2020 22:21:29
DataPoint Un-verified.	(b) (4)	14 Dec 2020 22:21:05
User entered '5 Oct 2020' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	14 Dec 2020 22:21:05
User opened query 'Per AE record subject was discharged 5-Oct-20. Did they administer IV Zofran at home?' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 16:02:47
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:06
User entered '6 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:10
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User entered empty.	System	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User entered empty.	System	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:37
User entered empty.	System	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 23:29:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 23:29:58
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Mar 2021 23:29:27 05 Mar 2021 23:29:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 20:08:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 20:08:03
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4)	20 Nov 2020 20:07:16 20 Nov 2020 20:06:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:12:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:24:42
Data point term sent to Coder User entered 'Acetaminophen'	System Alexander Mills (b) (4)	10 Nov 2020 22:08:06 10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:12:30
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per DM CLR: Please review the indication and note there is no corresponding AE record matching this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 21:30:13
Query 'Per DM CLR: Please review the indication and note there is no corresponding AE record matching this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'indication updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 23:29:14
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 23:29:07
User entered 'Con Medication related to procedure for AE #1 Spinal stenosis' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 23:29:07
User opened query 'Per DM CLR: Please review the indication and note there is no corresponding AE record matching this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:35:57
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:02:51
User closed query 'please revise to "pain from surgery for Spinal stenosis: or con-procedure: : pain from DISCECTOMY ANTERIOR CERVICAL SPINE FUSION procedure.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 16:02:48
Query 'please revise to "pain from surgery for Spinal stenosis: or con-procedure: : pain from DISCECTOMY ANTERIOR CERVICAL SPINE FUSION procedure.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:06:37
User entered 'pain from surgery for spinal stenosis' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:06:26
User opened query 'please revise to "pain from surgery for Spinal stenosis: or con-procedure: : pain from DISCECTOMY ANTERIOR CERVICAL SPINE FUSION procedure.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:16:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pain from spine surgery'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:28
User entered '650'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:30
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:33
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:39:38
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'every 6 hours??' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:06:08
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:06:01
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:35
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:41
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:42
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:46
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:47
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:50
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:51
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:37:39
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'this is the date the participant reports stop taking the medication' (Site from DM).	Xhoi Mitre (b) (4)	07 Apr 2021 22:44:08
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:33:20
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:48
Query 'Stop date not mentioned in hospital records. How was the stop date noted? Per DS pg 11: update on 10Nov20: subject was not taking this? Please check and update.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:09:46
User opened query 'Stop date not mentioned in hospital records. How was the stop date noted? Per DS pg 11: update on 10Nov20: subject was not taking this? Please check and update.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:22:29
User entered '6 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:54
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User entered empty.	System	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User entered empty.	System	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:42
User entered empty.	System	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 11:19:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 11:19:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Mar 2021 23:30:28 05 Mar 2021 23:30:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 11:55:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 11:55:56
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4)	20 Nov 2020 20:06:11 20 Nov 2020 20:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:10:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:10:44

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Dulcolax'	Coder Import (b) (4) (b) (4) System Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:10:44 10 Nov 2020 22:10:09 10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:28
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per DM CLR: Please note that there is no AE that matches Con Med #12 and #13 indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 21:30:20
Query 'Per DM CLR: Please note that there is no AE that matches Con Med #12 and #13 indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'indication updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 23:30:13
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 23:30:07
User entered 'Con Medication related to procedure for AE #1 Spinal stenosis' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:30:07
User opened query 'Per DM CLR: Please note that there is no AE that matches Con Med #12 and #13 indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:36:18
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:32
User entered 'Constipation'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:35
User entered '10'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:38
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:40
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:43
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:47
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:40
User closed query 'per source EMR: route is Rectal for suppository' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:38
Query 'per source EMR: route is Rectal for suppository' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:05:50
User entered 'Rectal (RECTAL)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:05:45
User opened query 'per source EMR: route is Rectal for suppository' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:11:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:11:01
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:50
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:54
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:07
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:15
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:19
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:37:56
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'this is the date that the participant reports that they stopped taking this medication' (Site from DM).	Xhoi Mitre (b) (4)	07 Apr 2021 22:44:46
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:33:44
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:23
User entered '6 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:25
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User entered empty.	System	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User entered empty.	System	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:47
User entered empty.	System	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:20
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:11:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 22:11:45
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 22:11:10
User entered 'Colace'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:23
	[REDACTED]	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:10:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:10:37
User entered 'No (N)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:10:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:10:31
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	19 Nov 2020 16:32:28
User entered 'Constipation'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:31
	[REDACTED]	
User entered '100'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:34
	[REDACTED]	
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	19 Nov 2020 16:32:36
User entered empty.	Alexander Mills (b) (4) [REDACTED]	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	19 Nov 2020 16:32:38
User entered 'as needed (PRN)'	Alexander Mills (b) (4) [REDACTED]	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:40
	[REDACTED]	
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:47
	[REDACTED]	
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:50
	[REDACTED]	
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:52
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:56
	[REDACTED]	
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:33:00
	[REDACTED]	
User entered 'Yes (Y)'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:07:22
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	19 Nov 2020 16:33:02
User entered empty.	Alexander Mills (b) (4) [REDACTED]	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:33:07
	[REDACTED]	
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Nov 2020 06:29:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Nov 2020 06:29:51
Data point term sent to Coder Coding entries removed.	System	20 Nov 2020 20:08:16
	Monica Feeley (b) (4)	20 Nov 2020 20:07:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:23:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 23:51:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 23:51:50
Data point term sent to Coder	System	10 Nov 2020 22:13:12
User entered 'Hydrocodone/ Acetaminophen'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:23:19
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:01:44
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 20:07:50
User entered 'PAIN FROM SURGERY FOR SPINAL STENOSIS' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:07:50
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'Pain from spine surgery'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:01:56
User closed query 'dose for hydrocodone is 7.5mg, together it is 7.5-325mg, please review and edit' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 16:01:53
Query 'dose for hydrocodone is 7.5mg, together it is 7.5-325mg, please review and edit' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:09:01
User entered '7.5-325' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:08:57
User opened query 'dose for hydrocodone is 7.5mg, together it is 7.5-325mg, please review and edit' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:25:13
User entered '325'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:17
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:20
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:39:47
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'every 6 hours' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:07:22
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:06:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:25
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:28
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:31
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:35
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:02:07
User closed query 'Per source EMR: start date is 05Oct20' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 16:02:03
Query 'Per source EMR: start date is 05Oct20' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:08:49
User entered '05 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:08:41
User opened query 'Per source EMR: start date is 05Oct20' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:16:05
Query 'per DS start date is 05Oct20, please review and edit' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:15:34
User opened query 'per DS start date is 05Oct20, please review and edit' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:26:05
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:26:54
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:02:20
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:21:15
User entered 'Yes (Y)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:02:26
User entered '14 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:21:15
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:26:56
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User entered empty.	System	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User entered empty.	System	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:08:02
User entered empty.	System	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 12:14:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 12:14:27
User closed query 'discharge summary mentions 5% lidocaine patch, please check' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:05
Query 'discharge summary mentions 5% lidocaine patch, please check' answered with 'medication notes state 4%. Was likely recorded into discharge summary incorrectly.' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:10:06
Data point term sent to Coder DataPoint Verified.	System	20 Nov 2020 20:09:17
	(b) (4), (b) (6)	19 Nov 2020 19:03:51
User opened query 'discharge summary mentions 5% lidocaine patch, please check' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:50:59
Data point term sent to Coder	System	10 Nov 2020 22:14:18
User entered 'Lidocaine Patch (4%)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:05
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:13:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:13:46
User entered 'No (N)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:13:46
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:13:41
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:09
User closed query 'Please check Indication.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:08
Query 'Please check Indication.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:09:15
User entered 'PAIN FROM SURGERY FOR SPINAL STENOSIS' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:09:11
User opened query 'Please check Indication.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:49:06
User entered 'Pain from spine'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:06
User entered '1'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:08
User entered 'Other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:10
User entered 'Application'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:12
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:14
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:17
User entered 'Topical (TOPICAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:19
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:26
User entered '4 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:28
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:20
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 20:18:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Monica Feeley (b) (4)	20 Nov 2020 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:30
User entered 'Yes (Y)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:18
User closed query 'Source EMR: stop date is 06Oct20, please review and edit. Also check discharge summary for 5% patch, add new entry as required.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:16
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).	System	20 Nov 2020 20:18:31
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	20 Nov 2020 20:18:19
User entered '06 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:18:19
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).	System	20 Nov 2020 20:18:07
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:18:07
Query 'Source EMR: stop date is 06Oct20, please review and edit. Also check discharge summary for 5% patch, add new entry as required.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:17:57
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	20 Nov 2020 20:10:38
User entered '06 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:10:38
User opened query 'Source EMR: stop date is 06Oct20, please review and edit. Also check discharge summary for 5% patch, add new entry as required.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:05:16
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:05:45
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User entered empty.	System	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User entered empty.	System	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:07:58
User entered empty.	System	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:35:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:24:06
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:00:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:08:40

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:52
	[REDACTED]	
User entered '02 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:19:49
	[REDACTED]	

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:54
	(b) (4), (b) (6)	
User closed query 'Source concomitant procedures log mentions: Discectomy anterior cervical spine fusion.: please check and and edit' (Site from CRA). Query 'Source concomitant procedures log mentions: Discectomy anterior cervical spine fusion.: please check and and edit' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	30 Oct 2020 14:28:38
	(b) (4)	
User entered 'Discectomy anterior cervical spine fusion' reason for change: Per Query Resolution DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 14:28:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:59
	(b) (4), (b) (6)	
User opened query 'Source concomitant procedures log mentions: Discectomy anterior cervical spine fusion.: please check and and edit' (Site from CRA). User entered 'Spinal Stenosis'	(b) (4), (b) (6)	23 Oct 2020 14:26:46
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Oct 2020 14:19:49
	(b) (4), (b) (6)	

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:52
	[REDACTED]	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Oct 2020 14:19:49
	[REDACTED]	

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:02

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:52
	[REDACTED]	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:19:49
	[REDACTED]	

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:35:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:39
User entered '07 Sep 2020'	Monica Feeley (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:35:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:42
User entered 'Cervical Spine MRI'	Monica Feeley (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:43
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:35:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:11:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:45
User entered empty.	Monica Feeley (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
	[REDACTED]	
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
	[REDACTED]	
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:00:36
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:35:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
User entered '14/Oct/2020 08:02'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:35:02

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.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
	[REDACTED]	
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:00:36
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:35:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
User entered '16/Oct/2020 11:08'	System	16 Oct 2020 15:08:22

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:35:02

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.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 20:51:23
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 15:08:22

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
	[REDACTED]	
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:35:02

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)	04 Mar 2021 18:17:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:58:43
User entered '0'	(b) (4), (b) (6)	02 Nov 2020 13:46:37

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
	[REDACTED]	
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:00:36
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:35:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:17:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '02/Nov/2020 13:46'	System	02 Nov 2020 13:46:37

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:35:02

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)	04 Mar 2021 18:17:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:58:43
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 13:46:37

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
	[REDACTED]	
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:35:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:17:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '11/Nov/2020 17:58'	System	11 Nov 2020 17:58:55

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:35:02

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)	04 Mar 2021 18:17:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 00:18:53
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 17:58:55

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
	[REDACTED]	
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
	[REDACTED]	
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:00:36
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:35:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:17:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '24/Nov/2020 00:19'	System	24 Nov 2020 00:19:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:35:02

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)	04 Mar 2021 18:17:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:00:36
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 00:19:08