

US3192345 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:41:58

All time stamps listed in this document are displayed in GMT

US3192345

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 23:52:39

Generated On: 09 Jun 2021 15:41:58

[Participant ID](#)

US3192345

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

US3192345

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input 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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 17:06:04

Generated On: 09 Jun 2021 15:41:58

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN SEP 2019
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)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 17:06:04

Generated On: 09 Jun 2021 15:41:58

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN JAN 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 17:06:04

Generated On: 09 Jun 2021 15:41:58

Condition	VITAMIN D DEFICIENT
Start date (dd MMM yyyy)	UN JAN 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) 18 Apr 2021 17:06:04

Generated On: 09 Jun 2021 15:41:58

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1991
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)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 17:06:04

Generated On: 09 Jun 2021 15:41:58

Condition	BOTOX
Start date (dd MMM yyyy)	UN UNK 2010
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)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 17:06:04

Generated On: 09 Jun 2021 15:41:58

Condition	STRESS CARDIOMYOPATHY
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	08:39 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 08:39
Height (xxx.x)	62.5 in
Weight (xxx.x)	197 lb
BMI (xxx.x)	35.53171 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 14 Feb 2021 02:44:23

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Date of assessment (dd MMM yyyy) 19 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1991

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 02:44:24

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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) 14 Feb 2021 02:44:24

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

What was the date of randomization? (dd MMM yyyy) 23 AUG 2020

What was the participant's randomization number? 187864

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Height	62.5 in
Weight	192 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Height	62.5 in
Weight	192 lb
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)	23 AUG 2020
Time of assessment (00:00-23:59)	14:32 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 14:32
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Height	62.5 in
Weight	192 lb
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)	23 AUG 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 15:50
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 23 AUG 2020

What was the treatment time? (00:00-23:59) 15:13 (24 HR)

Treatment Date and Time (derived) 23 AUG 2020 15:13

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) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 AUG 2020
Collection time (00:00-23:59)	14:53 (24 HR)
Collection date and time (derived)	23 AUG 2020 14:53

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Collection date (dd MMM yyyy)			23 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:51	23 AUG 2020 14:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

23 AUG 2020 15:43

PC Open Date & Time

23 AUG 2020 15:33

PC Close Date & Time

23 AUG 2020 18:03

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	23 AUG 2020 18:59
PC Open Date & Time	23 AUG 2020 18:58
PC Close Date & Time	24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 17:37

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

25 AUG 2020 18:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:08

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	27 AUG 2020 17:29
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 102.9 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 AUG 2020 20:23

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

102.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 20:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 8

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

100.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 AUG 2020 20:31

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 9

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

100.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 SEP 2020 02:52

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °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

02 SEP 2020 04:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

23 AUG 2020 15:44

PC Open Date & Time

23 AUG 2020 15:33

PC Close Date & Time

23 AUG 2020 18:03

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 19:00

PC Open Date & Time

23 AUG 2020 18:58

PC Close Date & Time

24 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 17:38

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 18:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:09

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 17:30

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:23

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 20:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

No ☒

Yes ☐

PC Time stamp	23 AUG 2020 15:44
PC Open Date & Time	23 AUG 2020 15:33
PC Close Date & Time	23 AUG 2020 18:03

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

No ☒

Yes ☐

PC Time stamp	23 AUG 2020 19:01
PC Open Date & Time	23 AUG 2020 18:58
PC Close Date & Time	24 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 17:39
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:07
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 17:09
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 17:30
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☒

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☒

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

No ☐

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

		Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 20:24	
PC Open Date & Time	28 AUG 2020 12:00	
PC Close Date & Time	29 AUG 2020 11:59	

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☒

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☒

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

		Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 20:12	
PC Open Date & Time	29 AUG 2020 12:00	
PC Close Date & Time	30 AUG 2020 11:59	

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 30 AUG 2020 20:31

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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 ☒

PC Time Stamp

01 SEP 2020 02:52

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 04:40

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 02 SEP 2020 21:21

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp 30 AUG 2020 20:31

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

01 SEP 2020 02:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

02 SEP 2020 04:40

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:54

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

04 SEP 2020 22:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

05 SEP 2020 17:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time stamp 30 AUG 2020 20:32

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 01 SEP 2020 02:53

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 10

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 SEP 2020 04:40

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 11

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 SEP 2020 21:22

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 12

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 03 SEP 2020 19:55

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 13

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 04 SEP 2020 22:12

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 14

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 05 SEP 2020 17:23

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 15

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

06 SEP 2020 18:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 30 AUG 2020 20:32

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 SEP 2020 02:53

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 02 SEP 2020 04:40

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

30 AUG 2020 20:32

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp

01 SEP 2020 02:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 10

Select one response below to indicate the level of your

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 ☐

PC Time stamp

02 SEP 2020 04:40

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 11

Select one response below to indicate the level of your

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 ☐

PC Time stamp

02 SEP 2020 21:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	30 AUG 2020 12:00
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PC Close Date & Time	31 AUG 2020 11:59
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PC Time stamp	30 AUG 2020 20:32
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US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

PC Time stamp 01 SEP 2020 02:53

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

PC Time stamp 02 SEP 2020 04:41

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	30 AUG 2020 20:33
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	01 SEP 2020 02:54
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	02 SEP 2020 04:41
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 21:22
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 19:55
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 22:12
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 17:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 18:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3192345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:50:35

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:50:35

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

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)	20 SEP 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	20 SEP 2020 11:27
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

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 (dd MMM yyyy)	20 SEP 2020
Time of assessment (00:00-23:59)	12:28 (24 HR)
Vital Signs Date and Time (derived)	20 SEP 2020 12:28
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3192345

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 SEP 2020

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

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 20 SEP 2020

What was the treatment time? (00:00-23:59) 11:55 (24 HR)

Treatment Date and Time (derived) 20 SEP 2020 11:55

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

US3192345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 SEP 2020
Collection time (00:00-23:59)	11:46 (24 HR)
Collection date and time (derived)	20 SEP 2020 11:46

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Collection date (dd MMM yyyy)			20 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:40	20 SEP 2020 11:40
Nasopharyngeal Swab 2	No		

US3192345

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:28

PC Open Date & Time

20 SEP 2020 12:15

PC Close Date & Time

20 SEP 2020 14:45

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 20 SEP 2020 20:12

PC Open Date & Time 20 SEP 2020 15:40

PC Close Date & Time 21 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 102.4 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 21 SEP 2020 18:06

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 SEP 2020 20:38

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 21:38

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 23:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 21:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

26 SEP 2020 22:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:29

PC Open Date & Time

20 SEP 2020 12:15

PC Close Date & Time

20 SEP 2020 14:45

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 20:18

PC Open Date & Time

20 SEP 2020 15:40

PC Close Date & Time

21 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

2

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

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

Yes ☒

No ☐

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

2

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 18:07

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:38

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 21:39

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 23:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 21:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 22:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

No ☒

Yes ☐

PC Time stamp	20 SEP 2020 12:29
PC Open Date & Time	20 SEP 2020 12:15
PC Close Date & Time	20 SEP 2020 14:45

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

No ☒

Yes ☐

PC Time stamp	20 SEP 2020 20:19
PC Open Date & Time	20 SEP 2020 15:40
PC Close Date & Time	21 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 18:08
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:39
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:40
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 23:00
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 21:21
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 22:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3192345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:23

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 15:25
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192345

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3192345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

15:35 (24 HR)

Collection date and time (derived)

22 OCT 2020 15:35

US3192345

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 02:44:24

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 12:00:13

Patient Cloud Open Date & Time

23 OCT 2020 00:01

Patient Cloud Close Date & Time

27 OCT 2020 23:59

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 OCT 2020 10:56:51
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 23:12:34

Patient Cloud Open Date & Time

06 NOV 2020 00:01

Patient Cloud Close Date & Time

10 NOV 2020 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
---	--

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

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 type="radio"/> Yes <input checked="" 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 checked="" 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 06:46:20
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 07:19:11

Patient Cloud Open Date & Time

01 DEC 2020 00:01

Patient Cloud Close Date & Time

05 DEC 2020 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 00:01:26

Patient Cloud Open Date & Time

08 DEC 2020 00:01

Patient Cloud Close Date & Time

12 DEC 2020 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 15:18:28
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 12:10:15

Patient Cloud Open Date & Time

22 DEC 2020 00:01

Patient Cloud Close Date & Time

26 DEC 2020 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

31 DEC 2020 22:34:26

Patient Cloud Open Date & Time

29 DEC 2020 00:01

Patient Cloud Close Date & Time

02 JAN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 17:54:22

Patient Cloud Open Date & Time

05 JAN 2021 00:01

Patient Cloud Close Date & Time

09 JAN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

12 JAN 2021 07:26:05

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 17:41:18

Patient Cloud Open Date & Time

19 JAN 2021 00:01

Patient Cloud Close Date & Time

23 JAN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 13:22:39

Patient Cloud Open Date & Time

26 JAN 2021 00:01

Patient Cloud Close Date & Time

30 JAN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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	02 FEB 2021 00:04:28
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 13:37:14

Patient Cloud Open Date & Time

09 FEB 2021 00:01

Patient Cloud Close Date & Time

13 FEB 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 FEB 2021 22:37:46
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 00:04:16

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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	02 MAR 2021 06:05:48
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 16:50:00

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

17 MAR 2021 19:02:57

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 07:36:25

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

30 MAR 2021 07:13:32

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 16:33:08

Patient Cloud Open Date & Time

06 APR 2021 00:01

Patient Cloud Close Date & Time

10 APR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☒

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 APR 2021 06:46:33

Patient Cloud Open Date & Time

13 APR 2021 00:01

Patient Cloud Close Date & Time

17 APR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☒

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

20 APR 2021 13:34:17

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☒

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 APR 2021 16:15:29

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐ 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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	25 MAY 2021 00:01
Patient Cloud Close Date & Time	29 MAY 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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°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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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°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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2021 00:01
Patient Cloud Close Date & Time	10 JUL 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2021 00:01
Patient Cloud Close Date & Time	17 JUL 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2021 00:01
Patient Cloud Close Date & Time	31 JUL 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2021 00:01
Patient Cloud Close Date & Time	14 AUG 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2021 00:01
Patient Cloud Close Date & Time	11 SEP 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2021 00:01
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Patient Cloud Close Date & Time	09 OCT 2021 23:59
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US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2021 00:01
Patient Cloud Close Date & Time	16 OCT 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2021 00:01
Patient Cloud Close Date & Time	23 OCT 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2021 00:01
Patient Cloud Close Date & Time	30 OCT 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 NOV 2021 00:01
Patient Cloud Close Date & Time	20 NOV 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 NOV 2021 00:01
Patient Cloud Close Date & Time	27 NOV 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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°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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 DEC 2021 00:01
Patient Cloud Close Date & Time	11 DEC 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2021 00:01
Patient Cloud Close Date & Time	18 DEC 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	21 DEC 2021 00:01
Patient Cloud Close Date & Time	25 DEC 2021 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JAN 2022 00:01
Patient Cloud Close Date & Time	22 JAN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 FEB 2022 00:01
Patient Cloud Close Date & Time	05 FEB 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 FEB 2022 00:01
Patient Cloud Close Date & Time	19 FEB 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 FEB 2022 00:01
Patient Cloud Close Date & Time	26 FEB 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 MAR 2022 00:01
Patient Cloud Close Date & Time	05 MAR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAR 2022 00:01
Patient Cloud Close Date & Time	19 MAR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 MAR 2022 00:01
Patient Cloud Close Date & Time	02 APR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 APR 2022 00:01
Patient Cloud Close Date & Time	30 APR 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2022 00:01
Patient Cloud Close Date & Time	09 JUL 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JUL 2022 00:01
Patient Cloud Close Date & Time	23 JUL 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2022 00:01
Patient Cloud Close Date & Time	30 JUL 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <input type="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	16 AUG 2022 00:01
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Patient Cloud Close Date & Time	20 AUG 2022 23:59
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US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 OCT 2022 00:01
Patient Cloud Close Date & Time	08 OCT 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2022 00:01
Patient Cloud Close Date & Time	15 OCT 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

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 ☐

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2022 00:01
Patient Cloud Close Date & Time	22 OCT 2022 23:59

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

Please 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="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2022 00:01
Patient Cloud Close Date & Time	29 OCT 2022 23:59

US3192345

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:41:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	02 MAR 2021 06:06:17

US3192345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:16:26

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:16:26

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 15:23:12

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 15:23:12

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 23:52:39

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 23:52:39

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 23:52:39

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 23:52:39

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 15:23:13

Generated On: 09 Jun 2021 15:41:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	24 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 15:23:13

Generated On: 09 Jun 2021 15:41:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 MAR 2021
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 13:40
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192345

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 15:23:13

Generated On: 09 Jun 2021 15:41:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3192345

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 15:23:13

Generated On: 09 Jun 2021 15:41:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	13:48 (24 HR)
Collection date and time (derived)	24 MAR 2021 13:48

US3192345

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 15:23:13

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 17:52:39

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 17:52:39

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192345

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3192345

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3192345

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:58

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

US3192345

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:41:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3192345

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 15:23:12

Generated On: 09 Jun 2021 15:41:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3192345

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 15:23:12

Generated On: 09 Jun 2021 15:41:58

Date of updated informed consent (*dd MMM yyyy*) 1 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 1 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3192345

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 15:23:12

Generated On: 09 Jun 2021 15:41:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 FEB 2021

Collection time (00:00-23:59)

15:37 (24 HR)

Collection date and time (derived)

1 FEB 2021 15:37

US3192345

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 15:23:12

Generated On: 09 Jun 2021 15:41:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00 - 23:59)	15:41
Collection Date and Time (derived)	1 FEB 2021 15:41

US3192345

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 16:18:20

Generated On: 09 Jun 2021 15:41:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	USA-US097-2020-MRNA-1273-P30 1000003
Adverse event	ACUTE PYELONEPHRITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	4 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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	

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

PATIENT REPORTED SHE WAS
EXPERIENCING LOW BACK
PAIN, FOLLOWED BY MUSCLE
ACHES AND FEVER. SHE
CALLED THE SITE, PI ADVISED
HER TO GO TO THE ER. SHE
WAS LATER DIAGNOSED WITH
A SEVERE KIDNEY INFECTION.
WAS TREATED WITH IV
ANITIBIOTICS.

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

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	USA-US097-2020-MRNA-1273-P30 1000003
Adverse event	UROSEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	04 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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	

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

PATIENT REPORTED SHE WAS
EXPERIENCING LOW BACK
PAIN, FOLLOWED BY MUSCLE
ACHES AND FEVER. SHE
CALLED THE SITE, PI ADVISED
HER TO GO TO THE ER. SHE
WAS LATER DIAGNOSED WITH
A SEVERE KIDNEY INFECTION.
WAS TREATED WITH IV
ANITIBIOTICS.

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID

Adverse event

GENERALIZED MUSCLE ACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	
Adverse event	JOINT ACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	2 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 20:43:25

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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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	
Adverse event	INTRACTABLE NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID

Adverse event

INTRACTABLE VOMITING

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	
Adverse event	BACTEREMIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID

Adverse event

MILD HYPONATREMIA

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)

29 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
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)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID

Adverse event

WORSENING HYPERTENSION

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)

28 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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)	_____

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

AEID	
Adverse event	FEVER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:41:58

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 23:52:39

Generated On: 09 Jun 2021 15:41:58

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication NEXIUM

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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)	UN JAN 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 13:43:58

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Name of Medication LOSARTEN/HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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 SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PREVENTATIVE

Dose per administration 81

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 (3)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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 SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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 JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FEVER, HEADACHE,
GENERALIZED MUSCLE ACHES,
JOINT ACHES. PAIN AT
INJECTION SITE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	Transdermal	<input type="checkbox"/>
	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 13:43:58

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FEVER, HEADACHE,
GENERALIZED MUSCLE ACHES,
JOINT ACHES. PAIN AT
INJECTION SITE

Dose per administration 800

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	Transdermal	<input type="checkbox"/>
	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)	21 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication IV ANTIBIOTIC

Prophylaxis Yes ☐
No ☒

Indication ACUTE PYELONEPHRITIS

Dose per administration UNK

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 (7)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication CIPRO

Prophylaxis Yes ☐
No ☒

Indication PYELONEPHRITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication FLUID RETENTION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration 15

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 (10)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 13:43:58

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Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication INTRACTABLE
NAUSEA/VOMITING

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

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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 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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT
INFECTION/BACTEREMIA

Dose per administration 1

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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US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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 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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

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

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 13:43:58

Generated On: 09 Jun 2021 15:41:58

	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)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Apr 2021 13:26:23

Generated On: 09 Jun 2021 15:41:58

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 17 Apr 2021 13:26:23

Generated On: 09 Jun 2021 15:41:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 AUG 2020	CHEST X-RAY	Diagnostic	
28 AUG 2020	CT ABDOMEN & PELVIS WITH CONTRAST	Diagnostic	
28 AUG 2020	EKG	Diagnostic	

US3192345

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:41:58

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

US3192345

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:41:58

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 ☐

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 19:44:44

Generated On: 09 Jun 2021 15:41:58

SAEID	USA-US097-2020-MRNA-1273-P301000003
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 19:44:44

Generated On: 09 Jun 2021 15:41:58

SAEID	USA-US097-2020-MRNA-1273-P301000003
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	21/SEP/2020 16:26
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

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 19:44:44

Generated On: 09 Jun 2021 15:41:58

SAEID	USA-US097-2020-MRNA-1273-P301000003
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/OCT/2020 11:31
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

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 19:44:44

Generated On: 09 Jun 2021 15:41:58

SAEID	USA-US097-2020-MRNA-1273-P301000003
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/NOV/2020 14:48
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

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 19:44:44

Generated On: 09 Jun 2021 15:41:58

SAEID	USA-US097-2020-MRNA-1273-P301000003
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/FEB/2021 08:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 19:44:44

Generated On: 09 Jun 2021 15:41:58

SAEID	USA-US097-2020-MRNA-1273-P301000003
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 10:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3192345 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192345

Form: Participant Creation

Generated On: 09 Jun 2021 15:41:58

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 16:44:57
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered 'US3192345'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 15:39:32

US3192345

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:33:37
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:32

US3192345

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:33:37
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 15:39:33

US3192345

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[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 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:33:37
User entered 'Clinic (Clinic)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:32

US3192345

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'SCRN'	System	28 Aug 2020 14:45:32

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User closed query 'Per CDM: Data is required. Please complete this form' (Site from DM).		31 Aug 2020 16:33:56
Query 'Per CDM: Data is required. Please complete this form' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes	28 Aug 2020 14:46:01
User opened query 'Per CDM: Data is required. Please complete this form' (Site from DM).	(b) (4)	
User entered (b) (6) 1953'	(b) (4), (b) (6)	28 Aug 2020 10:24:15
	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 15:39:34

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '67'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'YEARS'	System	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '67'	System	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered 'Female (F)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered 'l'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:55

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:29
User entered '19 Aug 2020'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Aug 2020'	System	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '2020'	System	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:29
User entered 'Amendment 1 (1)'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:29
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:29
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:29
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:29
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:05

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:35:29
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 15:39:33

US3192345

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'I'	System	23 Aug 2020 22:15:10

US3192345

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:36:33
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:10

US3192345

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:41:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User closed query 'Per source subject also has 'stress cardiomyopathy'. Please review and add to medical history in RAVE as applicable. Thanks' (Site from CRA).		21 Apr 2021 04:54:35
Query 'Per source subject also has 'stress cardiomyopathy'. Please review and add to medical history in RAVE as applicable. Thanks' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:41:05
User opened query 'Per source subject also has 'stress cardiomyopathy'. Please review and add to medical history in RAVE as applicable. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 17:55:10
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 01:36:42
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:29

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:15
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:41:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:41:40
Data point term sent to Coder	System	28 Aug 2020 14:40:10
User entered 'Hypertension'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:15
User entered 'un Sep 2019'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:15
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:15
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:15
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Sep 2019'	System	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '2019'	System	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	28 Aug 2020 14:39:43

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:16
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:42:47
Data point term sent to Coder	System	28 Aug 2020 14:41:11
User entered 'Gastroesophageal Reflux Disease'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:16
User entered 'un Jan 1980'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:16
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:16
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:16
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:16
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Jan 1980'	System	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '1980'	System	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	28 Aug 2020 14:40:29

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:45:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:45:43
Data point term sent to Coder	System	28 Aug 2020 14:45:21
User entered 'Vitamin D Deficient'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:18
User entered 'un Jan 2015'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:18
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:18
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:18
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Jan 2015'	System	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '2015'	System	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	28 Aug 2020 14:45:07

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 22:38:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'not deemed relevant by PI ' (Site from DM).	Norma Barrientos (b) (4)	21 Sep 2020 23:08:16
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 06:41:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 01:38:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 14:50:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 14:50:45
Data point term sent to Coder	System	28 Aug 2020 14:49:28
User entered 'Hysterectomy'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:02
User entered 'un UNK 1991'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:00
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:37:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:53:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User closed query 'Per source no end date is recorded. Please reconcile source and RAVE data. thanks' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Oct 2020 22:50:59
Query 'Per source no end date is recorded. Please reconcile source and RAVE data. thanks' answered with 'confirmed' (Site from CRA).	Cynthia Montgomery (b) (4)	09 Sep 2020 19:53:29
User opened query 'Per source no end date is recorded. Please reconcile source and RAVE data. thanks' (Site from CRA).	(b) (4), (b) (6)	04 Sep 2020 01:37:50
User entered 'un UNK 1991'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:53:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:37:54
DataPoint Verified.		04 Sep 2020 01:37:52
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Jan 1991'	System	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '1991'	System	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Jan 1991'	System	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '1991'	System	28 Aug 2020 14:48:50

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:54:11
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 22:53:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 22:53:17
Data point term sent to Coder	System	30 Mar 2021 22:52:28
User entered 'botox'	maggie Tono (b) (4) (b) (4)	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:54:11
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'un UNK 2010'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:54:11
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:54:11
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:54:11
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'un UNK 2010'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:54:11
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Jan 2010'	System	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '2010'	System	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Jan 2010'	System	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '2010'	System	30 Mar 2021 22:52:02

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	18 Apr 2021 17:06:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:03:46
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Stress cardiomyopathy, LLT: Stress cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 18:08:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 18:08:13
Data point term sent to Coder	System	17 Apr 2021 18:07:30
User entered 'Stress Cardiomyopathy'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	18 Apr 2021 17:06:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:03:46
User entered 'un UNK 2019'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	18 Apr 2021 17:06:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:03:46
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	18 Apr 2021 17:06:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:03:46
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	18 Apr 2021 17:06:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:03:46
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	18 Apr 2021 17:06:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:03:46
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'Jan 2019'	System	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '2019'	System	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered empty.	System	17 Apr 2021 18:07:21

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '19 Aug 2020'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '08:39'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '19 Aug 2020 08:39'	System	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '62.5' in	Yvonne De Los Reyes	28 Aug 2020 14:37:37
DataPoint set to visible.	(b) (4) System	23 Aug 2020 22:15:10

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '197' lb	Yvonne De Los Reyes	28 Aug 2020 14:37:37
DataPoint set to visible.	(b) (4) System	23 Aug 2020 22:15:10

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered '35.53171'	System	28 Aug 2020 14:37:37
DataPoint set to visible.	System	23 Aug 2020 22:15:10

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'kg/m2'	System	28 Aug 2020 14:37:37
DataPoint set to visible.	System	23 Aug 2020 22:15:10

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '97.1' F	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered 'Oral (Oral)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '70'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'bpm'	System	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '10'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'breaths/min'	System	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '124'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'mmHg'	System	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:38:56
User entered '83'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User entered 'mmHg'	System	28 Aug 2020 14:37:37

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00

US3192345

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00

US3192345

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:39:08
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:38:04

US3192345

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 11:13:39
		04 Sep 2020 01:39:08
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		01 Sep 2020 15:15:25
User entered '19 Aug 2020'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:38:04

US3192345

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered '19 Aug 2020'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:46:56

US3192345

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:46:56

US3192345

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:55:51
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User closed query 'Per DM CLR: Note,If No, what is the reason? = Other: HYSTERECTOMY, however, please confirm if reason can be recorded as one of the available prelisted choice (i.e. Surgically sterile). Please update as appropriate ensuring the procedure and undelying condition is also noted in the MedHistory eCRF page if appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:12:59
Query 'Per DM CLR: Note,If No, what is the reason? = Other: HYSTERECTOMY, however, please confirm if reason can be recorded as one of the available prelisted choice (i.e. Surgically sterile). Please update as appropriate ensuring the procedure and undelying condition is also noted in the MedHistory eCRF page if appropriate, otherwise clarify.' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	12 Oct 2020 13:24:10
DataPoint Un-verified.	Norma Barrientos (b) (4) (b) (4)	12 Oct 2020 13:23:58
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	12 Oct 2020 13:23:58
User opened query 'Per DM CLR: Note,If No, what is the reason? = Other: HYSTERECTOMY, however, please confirm if reason can be recorded as one of the available prelisted choice (i.e. Surgically sterile). Please update as appropriate ensuring the procedure and undelying condition is also noted in the MedHistory eCRF page if appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 15:20:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered 'Other (OTHER)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:46:56

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:55:53
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Un-verified.	(b) (4)	
	Norma Barrientos (b) (4)	12 Oct 2020 13:23:58
User entered empty; reason for change Data Entry Error	(b) (4)	
	Norma Barrientos (b) (4)	12 Oct 2020 13:23:58
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered 'Hysterectomy'	Yvonne De Los Reyes	28 Aug 2020 14:46:56
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
DataPoint Verified.		17 Apr 2021 17:55:59
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Un-verified.	(b) (4)	
	Norma Barrientos (b) (4)	12 Oct 2020 13:23:58
User entered 'un UNK 1991' reason for change:	(b) (4)	
Data Entry Error	Norma Barrientos (b) (4)	12 Oct 2020 13:23:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered empty.	Yvonne De Los Reyes	28 Aug 2020 14:46:56
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:46:56

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:46:56

US3192345

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:58

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:39:34
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:46:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

US3192345

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

[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 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

US3192345

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

US3192345

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

US3192345

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered 'I'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

US3192345

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

US3192345

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:00
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:40:04
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:39:06

US3192345

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:14
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:15:25

US3192345

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:14
User entered '23 Aug 2020'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:15:25

US3192345

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:14
User entered 'Clinic (Clinic)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:15:25

US3192345

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'VISIT1'	System	01 Sep 2020 15:15:25

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:20
User entered '23 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 22:09:11

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		11 Apr 2021 21:12:40
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '187864'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 22:09:11

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:31
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 22:09:11

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:49
User closed query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).		02 Sep 2020 03:52:26
Query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' answered with 'no' (Site from DM).	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:19:01
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:18:49
User opened query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:39:15

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:51
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:18:49

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:53
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:18:49

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:55
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:18:49

US3192345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:42:56
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:18:49

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:44:27
User entered '62.5' in	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:44:25
User entered '192' lb	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:44:27
User entered '62.5' in	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:44:25
User entered '192' lb	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User accepted default value 'Pre-Dose (PREDOSE)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:02
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:05
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	01 Sep 2020 15:22:53
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 15:22:53
User entered '23 Aug 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:53
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	01 Sep 2020 15:22:38
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 15:22:38
User entered '23 Aug 2002'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:04
User entered '14:32'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '23 Aug 2020 14:32'	System	01 Sep 2020 15:22:53
User entered '23 Aug 2002 14:32'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '97.8' F	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 15:23:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 15:23:28
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	01 Sep 2020 15:23:28
User entered 'Other (Other)' reason for change: Data maggie Tono Entry Error	(b) (4) (b) (4)	01 Sep 2020 15:23:28
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	01 Sep 2020 15:22:38
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 15:22:38
User entered empty.	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered 'infrared'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '84'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'bpm'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '14'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'breaths/min'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '130'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '81'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:44:27
User entered '62.5' in	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:44:25
User entered '192' lb	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User accepted default value 'Post-Dose (POSTDOSE)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '23 Aug 2020'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '15:50'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '23 Aug 2020 15:50'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '97.4' F	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 15:23:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 15:23:28
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	01 Sep 2020 15:23:28
User entered 'Other (Other)' reason for change: Data maggie Tono Entry Error	(b) (4) (b) (4)	01 Sep 2020 15:23:28
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	01 Sep 2020 15:22:38
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 15:22:38
User entered empty.	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered 'temporal'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '76'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'bpm'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '16'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'breaths/min'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '117'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:45:53
User entered '75'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	01 Sep 2020 15:22:38

US3192345

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:23
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:19:29

US3192345

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:23
User entered '23 Aug 2020'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:19:29

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:50
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:50
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:50
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'MRNA-1273 OR PLACEBO'	System	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:50
User entered '23 Aug 2020'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:50
User entered '15:13'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '23 Aug 2020 15:13'	System	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:50
User entered 'Left Arm (LEFT ARM)'	Saysamone Banks (b) (4) (b) (4)	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		04 Sep 2020 01:46:50
User entered 'ONCE'	System	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'INTRAMUSCULAR'	System	23 Aug 2020 22:15:35

US3192345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:57
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:17:33

US3192345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:57
User entered '23 Aug 2020'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:17:33

US3192345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:46:57
User entered '14:53'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:17:33

US3192345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '23 Aug 2020 14:53'	System	01 Sep 2020 15:17:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:47:01
User entered '23 Aug 2020'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:47:01
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:47:01
User entered '14:51'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '23 Aug 2020 14:51'	System	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:47:01
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:47:01
User entered empty.	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered empty.	System	01 Sep 2020 15:16:33

US3192345

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 01:47:06
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	01 Sep 2020 15:16:03

US3192345

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	01 Sep 2020 15:16:03

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:41:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9e101900-d3fe-4871-b56a-6cf9825600c9' User entered 'Yes (Y)'	System	23 Aug 2020 22:43:30
	System	23 Aug 2020 22:43:30

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:43:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9e101900-d3fe-4871-b56a-6cf9825600c9' User entered '97.4'	System	23 Aug 2020 22:43:30
	System	23 Aug 2020 22:43:30

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:43:21', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9e101900-d3fe-4871-b56a-6cf9825600c9' User entered 'No (N)'	System	23 Aug 2020 22:43:30
	System	23 Aug 2020 22:43:30

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:43:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9e101900-d3fe-4871-b56a-6cf9825600c9' User entered '23 Aug 2020 15:43'	System	23 Aug 2020 22:43:30
	System	23 Aug 2020 22:43:30

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 15:33'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 18:03'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T18:59:03', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f4a87cc9-3394-4f44-8a5d-43709d136917' User entered 'Yes (Y)'	System	24 Aug 2020 01:59:38
	System	24 Aug 2020 01:59:38

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T18:59:15', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f4a87cc9-3394-4f44-8a5d-43709d136917' User entered '97.8'	System	24 Aug 2020 01:59:38
	System	24 Aug 2020 01:59:38

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T18:59:21', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f4a87cc9-3394-4f44-8a5d-43709d136917'	System	24 Aug 2020 01:59:38
User entered 'No (N)'	System	24 Aug 2020 01:59:38

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T18:59:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f4a87cc9-3394-4f44-8a5d-43709d136917' User entered '23 Aug 2020 18:59'	System	24 Aug 2020 01:59:38
	System	24 Aug 2020 01:59:38

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 18:58'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 2'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:36:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '41492574-5e14-492b-978b-2465c66a8a80' User entered 'Yes (Y)'	System	25 Aug 2020 00:38:02
	System	25 Aug 2020 00:38:02

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:37:42', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '41492574-5e14-492b-978b-2465c66a8a80' User entered '98.7'	System	25 Aug 2020 00:38:02
	System	25 Aug 2020 00:38:02

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:37:49', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '41492574-5e14-492b-978b-2465c66a8a80'	System	25 Aug 2020 00:38:02
User entered 'No (N)'	System	25 Aug 2020 00:38:02

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:37:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '41492574-5e14-492b-978b-2465c66a8a80' User entered '24 Aug 2020 17:37'	System	25 Aug 2020 00:38:02
	System	25 Aug 2020 00:38:02

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 3'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:05:17', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '33b9058d-47d0-4221-85fa-a18601225c66' User entered 'Yes (Y)'	System	26 Aug 2020 01:06:04
	System	26 Aug 2020 01:06:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:05:23', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '33b9058d-47d0-4221-85fa-a18601225c66' User entered '97.4'	System	26 Aug 2020 01:06:04
	System	26 Aug 2020 01:06:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:05:38', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '33b9058d-47d0-4221-85fa-a18601225c66'	System	26 Aug 2020 01:06:04
User entered 'No (N)'	System	26 Aug 2020 01:06:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:05:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '33b9058d-47d0-4221-85fa-a18601225c66' User entered '25 Aug 2020 18:05'	System	26 Aug 2020 01:06:04
	System	26 Aug 2020 01:06:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 4'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:08:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd3c2c77d-c6ed-42e7-b7e7-2e34c4e1ce01' User entered 'Yes (Y)'	System	27 Aug 2020 00:08:47
	System	27 Aug 2020 00:08:47

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:08:36', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd3c2c77d-c6ed-42e7-b7e7-2e34c4e1ce01' User entered '98.7'	System	27 Aug 2020 00:08:47
	System	27 Aug 2020 00:08:47

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:08:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd3c2c77d-c6ed-42e7-b7e7-2e34c4e1ce01' User entered 'No (N)'	System	27 Aug 2020 00:08:47
	System	27 Aug 2020 00:08:47

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:08:45', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd3c2c77d-c6ed-42e7-b7e7-2e34c4e1ce01' User entered '26 Aug 2020 17:08'	System	27 Aug 2020 00:08:47
	System	27 Aug 2020 00:08:47

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 5'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:28:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '146906c9-72ca-4126-bb04-3624f18dcfb0' User entered 'Yes (Y)'	System	28 Aug 2020 00:29:33
	System	28 Aug 2020 00:29:33

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '146906c9-72ca-4126-bb04-3624f18dcfb0' User entered '98.9'	System	28 Aug 2020 00:29:33
	System	28 Aug 2020 00:29:33

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '146906c9-72ca-4126-bb04-3624f18dcfb0'	System	28 Aug 2020 00:29:33
User entered 'Yes (Y)'	System	28 Aug 2020 00:29:33

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4)	11 Sep 2020 05:24:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Cynthia Montgomery	09 Sep 2020 19:00:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '146906c9-72ca-4126-bb04-3624f18dcfb0'	(b) (4)	
User entered '1'	System	28 Aug 2020 00:29:33
	System	28 Aug 2020 00:29:33
	System	28 Aug 2020 00:29:33

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '146906c9-72ca-4126-bb04-3624f18dcfb0' User entered '0'	System	28 Aug 2020 00:29:33
	System	28 Aug 2020 00:29:33

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '146906c9-72ca-4126-bb04-3624f18dcfb0' User entered '27 Aug 2020 17:29'	System	28 Aug 2020 00:29:33
	System	28 Aug 2020 00:29:33

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 6'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:22:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7612b64b-df76-4d5f-b2a6-63c40abda4fe' User entered 'Yes (Y)'	System	29 Aug 2020 03:23:17
	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:22:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7612b64b-df76-4d5f-b2a6-63c40abda4fe' User entered '102.9'	System	29 Aug 2020 03:23:17
	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:22:58', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7612b64b-df76-4d5f-b2a6-63c40abda4fe' User entered 'Yes (Y)'	System	29 Aug 2020 03:23:17
	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4)	11 Sep 2020 05:25:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Cynthia Montgomery	09 Sep 2020 19:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7612b64b-df76-4d5f-b2a6-63c40abda4fe'	(b) (4)	
User entered '1'	System	29 Aug 2020 03:23:17
	System	29 Aug 2020 03:23:17
	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7612b64b-df76-4d5f-b2a6-63c40abda4fe' User entered '0'	System	29 Aug 2020 03:23:17
	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7612b64b-df76-4d5f-b2a6-63c40abda4fe' User entered '28 Aug 2020 20:23'	System	29 Aug 2020 03:23:17
	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 7'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:10:36', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ad69d547-97ee-45dd-9b4f-67fb8f6ed1ae' User entered 'Yes (Y)'	System	30 Aug 2020 03:11:04
	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:10:45', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ad69d547-97ee-45dd-9b4f-67fb8f6ed1ae' User entered '102.9'	System	30 Aug 2020 03:11:04
	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:10:52', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ad69d547-97ee-45dd-9b4f-67fb8f6ed1ae'	System	30 Aug 2020 03:11:04
User entered 'Yes (Y)'	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4)	11 Sep 2020 05:25:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Cynthia Montgomery	09 Sep 2020 19:01:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:10:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ad69d547-97ee-45dd-9b4f-67fb8f6ed1ae'	(b) (4)	
User entered '1'	System	30 Aug 2020 03:11:04
	System	30 Aug 2020 03:11:04
	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:10:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ad69d547-97ee-45dd-9b4f-67fb8f6ed1ae' User entered '0'	System	30 Aug 2020 03:11:04
	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ad69d547-97ee-45dd-9b4f-67fb8f6ed1ae' User entered '29 Aug 2020 20:11'	System	30 Aug 2020 03:11:04
	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:23:17
User entered 'Day 8'	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:30:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eff6b8ce-edb8-4f1f-a75a-c7ca8c5d2f26'	System	31 Aug 2020 03:31:13
User entered 'Yes (Y)'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:30:58', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eff6b8ce-edb8-4f1f-a75a-c7ca8c5d2f26' User entered '100.1'	System	31 Aug 2020 03:31:13
	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eff6b8ce-edb8-4f1f-a75a-c7ca8c5d2f26'	System	31 Aug 2020 03:31:13
User entered 'Yes (Y)'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).		11 Sep 2020 05:25:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Cynthia Montgomery	09 Sep 2020 19:01:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:05', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eff6b8ce-edb8-4f1f-a75a-c7ca8c5d2f26'	(b) (4)	
User entered '1'	System	31 Aug 2020 03:31:13
	System	31 Aug 2020 03:31:13
	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:05', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eff6b8ce-edb8-4f1f-a75a-c7ca8c5d2f26'	System	31 Aug 2020 03:31:13
User entered '0'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eff6b8ce-edb8-4f1f-a75a-c7ca8c5d2f26'	System	31 Aug 2020 03:31:13
User entered '30 Aug 2020 20:31'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:11:04
User entered 'Day 9'	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:24', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a0af7dd2-4c3e-4004-a25e-c05a482fca2b' User entered 'Yes (Y)'	System	01 Sep 2020 09:52:46
	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a0af7dd2-4c3e-4004-a25e-c05a482fca2b' User entered '100.1'	System	01 Sep 2020 09:52:46
	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a0af7dd2-4c3e-4004-a25e-c05a482fca2b'	System	01 Sep 2020 09:52:46
User entered 'Yes (Y)'	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 05:25:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a0af7dd2-4c3e-4004-a25e-c05a482fca2b' User entered '1'	Cynthia Montgomery (b) (4)	09 Sep 2020 19:01:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Sep 2020 09:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a0af7dd2-4c3e-4004-a25e-c05a482fca2b' User entered '1'	System	01 Sep 2020 09:52:46
User entered '1'	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a0af7dd2-4c3e-4004-a25e-c05a482fca2b' User entered '0'	System	01 Sep 2020 09:52:46
	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a0af7dd2-4c3e-4004-a25e-c05a482fca2b' User entered '01 Sep 2020 02:52'	System	01 Sep 2020 09:52:46
	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:31:13
User entered 'Day 10'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:39:35', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '315371e6-62f5-4f4e-bf53-0e2e4daf87d3' User entered 'Yes (Y)'	System	02 Sep 2020 11:40:00
	System	02 Sep 2020 11:40:00

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:39:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '315371e6-62f5-4f4e-bf53-0e2e4daf87d3' User entered '99.6'	System	02 Sep 2020 11:40:00
	System	02 Sep 2020 11:40:00

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:39:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '315371e6-62f5-4f4e-bf53-0e2e4daf87d3'	System	02 Sep 2020 11:40:00
User entered 'No (N)'	System	02 Sep 2020 11:40:00

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:39:54', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '315371e6-62f5-4f4e-bf53-0e2e4daf87d3' User entered '02 Sep 2020 04:39'	System	02 Sep 2020 11:40:00
	System	02 Sep 2020 11:40:00

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:43:46', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6ceb942-017b-46b0-a483-48dce7eb0784' User entered 'None (1)'	System	23 Aug 2020 22:44:09
	System	23 Aug 2020 22:44:09

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:43:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6ceb942-017b-46b0-a483-48dce7eb0784' User entered 'No (N)'	System	23 Aug 2020 22:44:09
	System	23 Aug 2020 22:44:09

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:43:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6ceb942-017b-46b0-a483-48dce7eb0784' User entered 'No (N)'	System	23 Aug 2020 22:44:09
	System	23 Aug 2020 22:44:09

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:03', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6ceb942-017b-46b0-a483-48dce7eb0784' User entered 'None (1)'	System	23 Aug 2020 22:44:09
	System	23 Aug 2020 22:44:09

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6ceb942-017b-46b0-a483-48dce7eb0784' User entered '23 Aug 2020 15:44'	System	23 Aug 2020 22:44:09
	System	23 Aug 2020 22:44:09

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 15:33'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 18:03'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T18:59:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'af331950-3c1b-4a2e-afc0-cfcc2b97453d' User entered 'None (1)'	System	24 Aug 2020 02:00:55
	System	24 Aug 2020 02:00:55

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:00:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'af331950-3c1b-4a2e-afc0-cfcc2b97453d' User entered 'No (N)'	System	24 Aug 2020 02:00:55
	System	24 Aug 2020 02:00:55

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:00:35', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'af331950-3c1b-4a2e-afc0-cfcc2b97453d' User entered 'No (N)'	System	24 Aug 2020 02:00:55
	System	24 Aug 2020 02:00:55

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:00:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'af331950-3c1b-4a2e-afc0-cfcc2b97453d' User entered 'None (1)'	System	24 Aug 2020 02:00:55
	System	24 Aug 2020 02:00:55

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:00:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'af331950-3c1b-4a2e-afc0-cfcc2b97453d' User entered '23 Aug 2020 19:00'	System	24 Aug 2020 02:00:55
	System	24 Aug 2020 02:00:55

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 18:58'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 2'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '795dca57-81ae-4b5a-8841-0564b6018672'	System	25 Aug 2020 00:38:39
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 00:38:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '795dca57-81ae-4b5a-8841-0564b6018672'	System	25 Aug 2020 00:38:39
User entered 'No (N)'	System	25 Aug 2020 00:38:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '795dca57-81ae-4b5a-8841-0564b6018672'	System	25 Aug 2020 00:38:39
User entered 'No (N)'	System	25 Aug 2020 00:38:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:30', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '795dca57-81ae-4b5a-8841-0564b6018672'	System	25 Aug 2020 00:38:39
User entered 'None (1)'	System	25 Aug 2020 00:38:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:36', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '795dca57-81ae-4b5a-8841-0564b6018672'	System	25 Aug 2020 00:38:39
User entered '24 Aug 2020 17:38'	System	25 Aug 2020 00:38:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 3'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:05:59', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '04bd0719-6219-44b3-aa17-775c3c7eef11' User entered 'None (1)'	System	26 Aug 2020 01:06:39
	System	26 Aug 2020 01:06:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '04bd0719-6219-44b3-aa17-775c3c7eef11'	System	26 Aug 2020 01:06:39
User entered 'No (N)'	System	26 Aug 2020 01:06:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '04bd0719-6219-44b3-aa17-775c3c7eef11' User entered 'No (N)'	System	26 Aug 2020 01:06:39
	System	26 Aug 2020 01:06:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:30', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '04bd0719-6219-44b3-aa17-775c3c7eef11' User entered 'None (1)'	System	26 Aug 2020 01:06:39
	System	26 Aug 2020 01:06:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:35', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '04bd0719-6219-44b3-aa17-775c3c7eef11' User entered '25 Aug 2020 18:06'	System	26 Aug 2020 01:06:39
	System	26 Aug 2020 01:06:39

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 4'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:08:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b40de1be-5fe1-42df-9f84-e3b51ddb971d' User entered 'None (1)'	System	27 Aug 2020 00:09:21
	System	27 Aug 2020 00:09:21

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:08:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b40de1be-5fe1-42df-9f84-e3b51ddb971d' User entered 'No (N)'	System	27 Aug 2020 00:09:21
	System	27 Aug 2020 00:09:21

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:08:59', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b40de1be-5fe1-42df-9f84-e3b51ddb971d' User entered 'No (N)'	System	27 Aug 2020 00:09:21
	System	27 Aug 2020 00:09:21

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b40de1be-5fe1-42df-9f84-e3b51ddb971d' User entered 'None (1)'	System	27 Aug 2020 00:09:21
	System	27 Aug 2020 00:09:21

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b40de1be-5fe1-42df-9f84-e3b51ddb971d' User entered '26 Aug 2020 17:09'	System	27 Aug 2020 00:09:21
	System	27 Aug 2020 00:09:21

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 5'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:36', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e62315f2-cc3f-4610-b906-607ac0dc0c20'	System	28 Aug 2020 00:30:10
User entered 'None (1)'	System	28 Aug 2020 00:30:10

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:40', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e62315f2-cc3f-4610-b906-607ac0dc0c20' User entered 'No (N)'	System	28 Aug 2020 00:30:10
	System	28 Aug 2020 00:30:10

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:29:42', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e62315f2-cc3f-4610-b906-607ac0dc0c20' User entered 'No (N)'	System	28 Aug 2020 00:30:10
	System	28 Aug 2020 00:30:10

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e62315f2-cc3f-4610-b906-607ac0dc0c20'	System	28 Aug 2020 00:30:10
User entered 'None (1)'	System	28 Aug 2020 00:30:10

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:06', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e62315f2-cc3f-4610-b906-607ac0dc0c20' User entered '27 Aug 2020 17:30'	System	28 Aug 2020 00:30:10
	System	28 Aug 2020 00:30:10

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 6'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:23', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f77ca08-1bcb-4282-b072-4660a1d0e6a6' User entered 'None (1)'	System	29 Aug 2020 03:23:41
	System	29 Aug 2020 03:23:41

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f77ca08-1bcb-4282-b072-4660a1d0e6a6' User entered 'No (N)'	System	29 Aug 2020 03:23:41
	System	29 Aug 2020 03:23:41

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f77ca08-1bcb-4282-b072-4660a1d0e6a6' User entered 'No (N)'	System	29 Aug 2020 03:23:41
	System	29 Aug 2020 03:23:41

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f77ca08-1bcb-4282-b072-4660a1d0e6a6' User entered 'None (1)'	System	29 Aug 2020 03:23:41
	System	29 Aug 2020 03:23:41

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:23:38', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f77ca08-1bcb-4282-b072-4660a1d0e6a6' User entered '28 Aug 2020 20:23'	System	29 Aug 2020 03:23:41
	System	29 Aug 2020 03:23:41

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 7'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '77d7c42e-07d0-4a61-9af5-acd921d3da1b' User entered 'None (1)'	System	30 Aug 2020 03:11:36
	System	30 Aug 2020 03:11:36

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '77d7c42e-07d0-4a61-9af5-acd921d3da1b' User entered 'No (N)'	System	30 Aug 2020 03:11:36
	System	30 Aug 2020 03:11:36

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:15', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '77d7c42e-07d0-4a61-9af5-acd921d3da1b' User entered 'No (N)'	System	30 Aug 2020 03:11:36
	System	30 Aug 2020 03:11:36

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:21', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '77d7c42e-07d0-4a61-9af5-acd921d3da1b' User entered 'None (1)'	System	30 Aug 2020 03:11:36
	System	30 Aug 2020 03:11:36

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '77d7c42e-07d0-4a61-9af5-acd921d3da1b' User entered '29 Aug 2020 20:11'	System	30 Aug 2020 03:11:36
	System	30 Aug 2020 03:11:36

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:32', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered 'None (0)'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:35', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered 'None (0)'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:37', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered 'None (0)'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered 'None (0)'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered 'None (0)'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered 'None (0)'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered 'No (N)'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T15:44:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '38d837b6-0c05-4e98-8831-37c05bc6e5c3' User entered '23 Aug 2020 15:44'	System	23 Aug 2020 22:44:59
	System	23 Aug 2020 22:44:59

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 15:33'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 18:03'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:00:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588' User entered 'None (0)'	System	24 Aug 2020 02:01:22
	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:00:59', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588' User entered 'None (0)'	System	24 Aug 2020 02:01:22
	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:01:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588' User entered 'None (0)'	System	24 Aug 2020 02:01:22
	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:01:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588' User entered 'None (0)'	System	24 Aug 2020 02:01:22
	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:01:06', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588' User entered 'None (0)'	System	24 Aug 2020 02:01:22
	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:01:09', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588' User entered 'None (0)'	System	24 Aug 2020 02:01:22
	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:01:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588'	System	24 Aug 2020 02:01:22
User entered 'No (N)'	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-23T19:01:20', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd419baa5-fd4b-4bfb-b792-d7c717864588'	System	24 Aug 2020 02:01:22
User entered '23 Aug 2020 19:01'	System	24 Aug 2020 02:01:22

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Aug 2020 18:58'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 2'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:45', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered 'None (0)'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:49', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered 'None (0)'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:54', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered 'None (0)'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:38:58', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered 'None (0)'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:39:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered 'None (0)'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:39:03', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered 'None (0)'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:39:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered 'No (N)'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-24T17:39:09', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2e9cc2f-c21a-4ac1-ab24-e41ee3fa8989' User entered '24 Aug 2020 17:39'	System	25 Aug 2020 00:39:15
	System	25 Aug 2020 00:39:15

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 3'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered 'None (0)'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:46', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered 'None (0)'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:48', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered 'None (0)'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered 'None (0)'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered 'None (0)'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:54', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered 'None (0)'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:06:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered 'No (N)'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-25T18:07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ca409e5-8cdd-44c5-93c5-ae60488f891b' User entered '25 Aug 2020 18:07'	System	26 Aug 2020 01:07:02
	System	26 Aug 2020 01:07:02

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 4'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:22', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3' User entered 'None (0)'	System	27 Aug 2020 00:09:47
	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3' User entered 'None (0)'	System	27 Aug 2020 00:09:47
	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:30', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3'	System	27 Aug 2020 00:09:47
User entered 'No interference with activity (1)'	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3' User entered 'None (0)'	System	27 Aug 2020 00:09:47
	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:36', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3' User entered 'None (0)'	System	27 Aug 2020 00:09:47
	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:38', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3' User entered 'None (0)'	System	27 Aug 2020 00:09:47
	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3' User entered 'No (N)'	System	27 Aug 2020 00:09:47
	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-26T17:09:43', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1ba09409-95eb-4611-ae7a-13380e0395d3' User entered '26 Aug 2020 17:09'	System	27 Aug 2020 00:09:47
	System	27 Aug 2020 00:09:47

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 5'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417' User entered 'None (0)'	System	28 Aug 2020 00:30:53
	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417'	System	28 Aug 2020 00:30:53
User entered 'No interference with activity (1)'	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417'	System	28 Aug 2020 00:30:53
User entered 'Some interference with activity (2)'	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417'	System	28 Aug 2020 00:30:53
User entered 'No interference with activity (1)'	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:35', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417' User entered 'None (0)'	System	28 Aug 2020 00:30:53
	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:42', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417'	System	28 Aug 2020 00:30:53
User entered 'No interference with activity (1)'	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:45', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417' User entered 'No (N)'	System	28 Aug 2020 00:30:53
	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-27T17:30:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6546c3b-5c26-4de5-b40d-8bfad86f6417' User entered '27 Aug 2020 17:30'	System	28 Aug 2020 00:30:53
	System	28 Aug 2020 00:30:53

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 6'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:03', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784'	System	29 Aug 2020 03:24:46
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784'	System	29 Aug 2020 03:24:46
User entered 'Significant; prevents daily activity (3)'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:17', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784'	System	29 Aug 2020 03:24:46
User entered 'Significant; prevents daily activity (3)'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:21', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784'	System	29 Aug 2020 03:24:46
User entered 'Significant; prevents daily activity (3)'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784'	System	29 Aug 2020 03:24:46
User entered 'Prevents daily activity, requires outpatient IV hydration (3)'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:33', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784'	System	29 Aug 2020 03:24:46
User entered 'Prevents daily activity and requires medical attention (3)'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784' User entered 'Yes (Y)'	System	29 Aug 2020 03:24:46
	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-28T20:24:43', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0a0809eb-ce05-41c4-8d3b-1a850fb61784' User entered '28 Aug 2020 20:24'	System	29 Aug 2020 03:24:46
	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 7'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5'	System	30 Aug 2020 03:12:21
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:43', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5'	System	30 Aug 2020 03:12:21
User entered 'Significant; prevents daily activity (3)'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5'	System	30 Aug 2020 03:12:21
User entered 'Significant; prevents daily activity (3)'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5'	System	30 Aug 2020 03:12:21
User entered 'Significant; prevents daily activity (3)'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:54', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5'	System	30 Aug 2020 03:12:21
User entered 'Prevents daily activity, requires outpatient IV hydration (3)'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:11:59', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5'	System	30 Aug 2020 03:12:21
User entered 'Prevents daily activity and requires medical attention (3)'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:12:03', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5' User entered 'Yes (Y)'	System	30 Aug 2020 03:12:21
	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-29T20:12:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '277cc4eb-f53d-46b3-94ac-8d91d956d1b5' User entered '29 Aug 2020 20:12'	System	30 Aug 2020 03:12:21
	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:24:46
User entered 'Day 8'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:24', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9b2ab65c-e359-485a-b3eb-b6f9ee635ea1'	System	31 Aug 2020 03:31:33
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:31:33

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:31', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9b2ab65c-e359-485a-b3eb-b6f9ee635ea1' User entered '30 Aug 2020 20:31'	System	31 Aug 2020 03:31:33
	System	31 Aug 2020 03:31:33

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:12:21
User entered 'Day 9'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '78243205-60be-4f6f-8838-1e6c01a44ae1'	System	01 Sep 2020 09:52:55
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		01 Sep 2020 09:52:55

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '78243205-60be-4f6f-8838-1e6c01a44ae1' User entered '01 Sep 2020 02:52'	System	01 Sep 2020 09:52:55
	System	01 Sep 2020 09:52:55

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:31:33
User entered 'Day 10'	System	31 Aug 2020 03:31:33

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '182c8b35-0b5c-4a11-9c93-95d361503a74'	System	02 Sep 2020 11:40:10
User entered 'No interference with activity (1)'	System	02 Sep 2020 11:40:10

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '182c8b35-0b5c-4a11-9c93-95d361503a74'	System	02 Sep 2020 11:40:10
User entered '02 Sep 2020 04:40'	System	02 Sep 2020 11:40:10

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:31:33

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:31:33

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	01 Sep 2020 09:52:55
User entered 'Day 11'	System	01 Sep 2020 09:52:55

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:21:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6d79056f-1e20-42df-b099-51fe146ab1d3' User entered 'None (0)'	System	03 Sep 2020 04:22:05
	System	03 Sep 2020 04:22:05

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:21:59', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6d79056f-1e20-42df-b099-51fe146ab1d3' User entered '02 Sep 2020 21:21'	System	03 Sep 2020 04:22:05
	System	03 Sep 2020 04:22:05

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 09:52:55

US3192345

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 09:52:55

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:24:46
User entered 'Day 8'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:49', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'dc960a89-33fa-4d7d-b4ba-057ad9a76ee0'	System	31 Aug 2020 03:31:56
User entered 'Significant; prevents daily activity (3)'	System	31 Aug 2020 03:31:56

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:31:52', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'dc960a89-33fa-4d7d-b4ba-057ad9a76ee0' User entered '30 Aug 2020 20:31'	System	31 Aug 2020 03:31:56
	System	31 Aug 2020 03:31:56

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:12:21
User entered 'Day 9'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:52:58', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a42357b9-6618-4bee-85cc-b23010087109'	System	01 Sep 2020 09:53:06
User entered 'Some interference with activity (2)'	System	01 Sep 2020 09:53:06

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a42357b9-6618-4bee-85cc-b23010087109' User entered '01 Sep 2020 02:53'	System	01 Sep 2020 09:53:06
	System	01 Sep 2020 09:53:06

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:31:56
User entered 'Day 10'	System	31 Aug 2020 03:31:56

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '817d5f83-1bc8-4187-a9ba-bbe5ea68312f' User entered 'Some interference with activity (2)'	System	02 Sep 2020 11:40:22
	System	02 Sep 2020 11:40:22

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:17', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '817d5f83-1bc8-4187-a9ba-bbe5ea68312f' User entered '02 Sep 2020 04:40'	System	02 Sep 2020 11:40:22
	System	02 Sep 2020 11:40:22

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:31:56

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:31:56

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	01 Sep 2020 09:53:06
User entered 'Day 11'	System	01 Sep 2020 09:53:06

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:05', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'aa54dd5f-4005-49be-8726-35798bd2fc17'	System	03 Sep 2020 04:22:16
User entered 'Some interference with activity (2)'	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:09', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'aa54dd5f-4005-49be-8726-35798bd2fc17' User entered '02 Sep 2020 21:22'	System	03 Sep 2020 04:22:16
	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 09:53:06

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 09:53:06

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	02 Sep 2020 11:40:22
User entered 'Day 12'	System	02 Sep 2020 11:40:22

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-03T19:54:40', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'da45596d-0078-4c3a-9f18-a2eda50296c3'	System	04 Sep 2020 02:54:48
User entered 'Some interference with activity (2)'	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-03T19:54:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'da45596d-0078-4c3a-9f18-a2eda50296c3' User entered '03 Sep 2020 19:54'	System	04 Sep 2020 02:54:48
	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 11:40:22

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 11:40:22

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	03 Sep 2020 04:22:16
User entered 'Day 13'	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-04T22:12:06', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1c57bbf0-574a-4246-badc-a6df8b647ec3'	System	05 Sep 2020 05:12:12
User entered 'Some interference with activity (2)'	System	05 Sep 2020 05:12:12

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-04T22:12:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1c57bbf0-574a-4246-badc-a6df8b647ec3' User entered '04 Sep 2020 22:12'	System	05 Sep 2020 05:12:12
	System	05 Sep 2020 05:12:12

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	04 Sep 2020 02:54:48
User entered 'Day 14'	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-05T17:23:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '094ea4fe-a191-44df-8585-6b2b59d6bd41'	System	06 Sep 2020 00:23:34
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:23:34

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-05T17:23:31', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '094ea4fe-a191-44df-8585-6b2b59d6bd41' User entered '05 Sep 2020 17:23'	System	06 Sep 2020 00:23:34
	System	06 Sep 2020 00:23:34

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	05 Sep 2020 05:12:12
User entered 'Day 15'	System	05 Sep 2020 05:12:12

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-06T18:43:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'aca45f90-be38-4f50-b27c-29df7b4aaf97' User entered 'None (0)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-06T18:43:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'aca45f90-be38-4f50-b27c-29df7b4aaf97'	System	07 Sep 2020 01:44:00
User entered '06 Sep 2020 18:43'	System	07 Sep 2020 01:44:00

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 05:12:12

US3192345

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 05:12:12

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:24:46
User entered 'Day 8'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'db1f2ee5-ce58-443b-a9ee-d6f72d5b2e39'	System	31 Aug 2020 03:32:11
User entered 'Significant; prevents daily activity (3)'	System	31 Aug 2020 03:32:11

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'db1f2ee5-ce58-443b-a9ee-d6f72d5b2e39' User entered '30 Aug 2020 20:32'	System	31 Aug 2020 03:32:11
	System	31 Aug 2020 03:32:11

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:12:21
User entered 'Day 9'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:05', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'daecbd4f-c528-42b4-a174-328f3e35b56c'	System	01 Sep 2020 09:53:17
User entered 'Some interference with activity (2)'	System	01 Sep 2020 09:53:17

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:16', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'daecbd4f-c528-42b4-a174-328f3e35b56c' User entered '01 Sep 2020 02:53'	System	01 Sep 2020 09:53:17
	System	01 Sep 2020 09:53:17

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:32:11
User entered 'Day 10'	System	31 Aug 2020 03:32:11

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:27', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '3ade6abd-daf1-4f64-b11f-bbb81dfce08f' User entered 'No interference with activity (1)'	System	02 Sep 2020 11:40:34
	System	02 Sep 2020 11:40:34

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:31', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '3ade6abd-daf1-4f64-b11f-bbb81dfce08f' User entered '02 Sep 2020 04:40'	System	02 Sep 2020 11:40:34
	System	02 Sep 2020 11:40:34

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:32:11

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:32:11

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	01 Sep 2020 09:53:17
User entered 'Day 11'	System	01 Sep 2020 09:53:17

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:19', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e3b8697d-af22-4ba0-bb52-ba845c2bd1a9'	System	03 Sep 2020 04:22:26
User entered 'No interference with activity (1)'	System	03 Sep 2020 04:22:26

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:22', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e3b8697d-af22-4ba0-bb52-ba845c2bd1a9' User entered '02 Sep 2020 21:22'	System	03 Sep 2020 04:22:26
	System	03 Sep 2020 04:22:26

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 09:53:17

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 09:53:17

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	02 Sep 2020 11:40:34
User entered 'Day 12'	System	02 Sep 2020 11:40:34

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-03T19:54:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '3e87a3ad-e3fe-4bac-8002-12f897517ad6'	System	04 Sep 2020 02:55:03
User entered 'No interference with activity (1)'	System	04 Sep 2020 02:55:03

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-03T19:55:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '3e87a3ad-e3fe-4bac-8002-12f897517ad6' User entered '03 Sep 2020 19:55'	System	04 Sep 2020 02:55:03
	System	04 Sep 2020 02:55:03

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 11:40:34

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 11:40:34

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	03 Sep 2020 04:22:26
User entered 'Day 13'	System	03 Sep 2020 04:22:26

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-04T22:12:13', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4c88ae25-a835-43dd-bd46-8774bda7ff1c'	System	05 Sep 2020 05:12:19
User entered 'No interference with activity (1)'	System	05 Sep 2020 05:12:19

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-04T22:12:17', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4c88ae25-a835-43dd-bd46-8774bda7ff1c' User entered '04 Sep 2020 22:12'	System	05 Sep 2020 05:12:19
	System	05 Sep 2020 05:12:19

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 04:22:26

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 04:22:26

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	04 Sep 2020 02:55:03
User entered 'Day 14'	System	04 Sep 2020 02:55:03

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-05T17:23:37', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '17eee9f6-56ed-46a1-b981-aa9e256ffe6e'	System	06 Sep 2020 00:23:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:23:44

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-05T17:23:40', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '17eee9f6-56ed-46a1-b981-aa9e256ffe6e' User entered '05 Sep 2020 17:23'	System	06 Sep 2020 00:23:44
	System	06 Sep 2020 00:23:44

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 02:55:03

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 02:55:03

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	05 Sep 2020 05:12:19
User entered 'Day 15'	System	05 Sep 2020 05:12:19

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-06T18:44:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0884136e-2ca1-4915-ade3-3c8c1eeb1383' User entered 'None (0)'	System	07 Sep 2020 01:44:06
	System	07 Sep 2020 01:44:06

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-06T18:44:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0884136e-2ca1-4915-ade3-3c8c1eeb1383' User entered '06 Sep 2020 18:44'	System	07 Sep 2020 01:44:06
	System	07 Sep 2020 01:44:06

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 05:12:19

US3192345

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 05:12:19

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:24:46
User entered 'Day 8'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:20', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a1d080fb-c42e-42a3-a83b-c2fc9bc659e9'	System	31 Aug 2020 03:32:27
User entered 'Some interference with activity (2)'	System	31 Aug 2020 03:32:27

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:24', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a1d080fb-c42e-42a3-a83b-c2fc9bc659e9' User entered '30 Aug 2020 20:32'	System	31 Aug 2020 03:32:27
	System	31 Aug 2020 03:32:27

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:12:21
User entered 'Day 9'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:24', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c368366a-1770-4794-a4ca-b7c25aa9e113'	System	01 Sep 2020 09:53:30
User entered 'No interference with activity (1)'	System	01 Sep 2020 09:53:30

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:27', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c368366a-1770-4794-a4ca-b7c25aa9e113' User entered '01 Sep 2020 02:53'	System	01 Sep 2020 09:53:30
	System	01 Sep 2020 09:53:30

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:32:27
User entered 'Day 10'	System	31 Aug 2020 03:32:27

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:40', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '72ccfc4e-d9ad-4f2c-b892-5f7bf0a63fb8' User entered 'None (0)'	System	02 Sep 2020 11:40:46
	System	02 Sep 2020 11:40:46

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '72ccfc4e-d9ad-4f2c-b892-5f7bf0a63fb8'	System	02 Sep 2020 11:40:46
User entered '02 Sep 2020 04:40'	System	02 Sep 2020 11:40:46

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:32:27

US3192345

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:32:27

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:24:46
User entered 'Day 8'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c1b13508-833a-42bc-8778-8e43dffa7ed0'	System	31 Aug 2020 03:32:44
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	31 Aug 2020 03:32:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:42', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c1b13508-833a-42bc-8778-8e43dffa7ed0' User entered '30 Aug 2020 20:32'	System	31 Aug 2020 03:32:44
	System	31 Aug 2020 03:32:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:12:21
User entered 'Day 9'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:37', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '079367cb-960a-4c27-a17d-1e9154d0840c'	System	01 Sep 2020 09:53:44
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	01 Sep 2020 09:53:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '079367cb-960a-4c27-a17d-1e9154d0840c' User entered '01 Sep 2020 02:53'	System	01 Sep 2020 09:53:44
	System	01 Sep 2020 09:53:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:32:44
User entered 'Day 10'	System	31 Aug 2020 03:32:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6e237d80-6b2f-4aa7-9ca7-964d77c1c743'	System	02 Sep 2020 11:40:58
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Sep 2020 11:40:58

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6e237d80-6b2f-4aa7-9ca7-964d77c1c743' User entered '02 Sep 2020 04:40'	System	02 Sep 2020 11:40:58
	System	02 Sep 2020 11:40:58

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:32:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:32:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	01 Sep 2020 09:53:44
User entered 'Day 11'	System	01 Sep 2020 09:53:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ba16b1ad-b095-4431-a717-b10747a9b42d' User entered 'None (0)'	System	03 Sep 2020 04:22:37
	System	03 Sep 2020 04:22:37

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:33', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ba16b1ad-b095-4431-a717-b10747a9b42d' User entered '02 Sep 2020 21:22'	System	03 Sep 2020 04:22:37
	System	03 Sep 2020 04:22:37

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 09:53:44

US3192345

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 09:53:44

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:24:46
User entered 'Day 8'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a32b89dd-1a07-417f-9fbd-edaf23490006'	System	31 Aug 2020 03:32:57
User entered 'Some interference with activity not requiring medical attention (2)'	System	31 Aug 2020 03:32:57

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:24:46

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:32:54', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a32b89dd-1a07-417f-9fbd-edaf23490006' User entered '30 Aug 2020 20:32'	System	31 Aug 2020 03:32:57
	System	31 Aug 2020 03:32:57

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:12:21
User entered 'Day 9'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c091b95d-e18c-46b3-89c2-c696ff2929ff'	System	01 Sep 2020 09:53:49
User entered 'Some interference with activity not requiring medical attention (2)'	System	01 Sep 2020 09:53:49

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:12:21

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c091b95d-e18c-46b3-89c2-c696ff2929ff' User entered '01 Sep 2020 02:53'	System	01 Sep 2020 09:53:49
	System	01 Sep 2020 09:53:49

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:32:57
User entered 'Day 10'	System	31 Aug 2020 03:32:57

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 09 Jun 2021 15:41:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:40:58', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7ca791aa-1a84-4ab9-9fc1-0a81a4d76aee' User entered 'None (0)'	System	02 Sep 2020 11:41:05
	System	02 Sep 2020 11:41:05

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:32:57

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:32:57

US3192345

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:41:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7ca791aa-1a84-4ab9-9fc1-0a81a4d76aee'	System	02 Sep 2020 11:41:05
User entered '02 Sep 2020 04:41'	System	02 Sep 2020 11:41:05

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	29 Aug 2020 03:23:17
User entered 'Day 8'	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:33:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2d96f669-2e9a-478a-a890-ad46232560ac' User entered 'Yes (Y)'	System	31 Aug 2020 03:33:12
	System	31 Aug 2020 03:33:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-08-30T20:33:09', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2d96f669-2e9a-478a-a890-ad46232560ac' User entered '30 Aug 2020 20:33'	System	31 Aug 2020 03:33:12
	System	31 Aug 2020 03:33:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 03:23:17

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	30 Aug 2020 03:11:04
User entered 'Day 9'	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:53:58', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9d142621-75e4-4234-9ee1-9a0b1a62d722'	System	01 Sep 2020 09:54:05
User entered 'Yes (Y)'	System	01 Sep 2020 09:54:05

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-01T02:54:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9d142621-75e4-4234-9ee1-9a0b1a62d722'	System	01 Sep 2020 09:54:05
User entered '01 Sep 2020 02:54'	System	01 Sep 2020 09:54:05

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 03:11:04

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	31 Aug 2020 03:31:13
User entered 'Day 10'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:41:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '39372550-ccdf-419a-971c-6862a5dd728a' User entered 'Yes (Y)'	System	02 Sep 2020 11:41:12
	System	02 Sep 2020 11:41:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T04:41:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '39372550-ccdf-419a-971c-6862a5dd728a' User entered '02 Sep 2020 04:41'	System	02 Sep 2020 11:41:12
	System	02 Sep 2020 11:41:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:31:13

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	01 Sep 2020 09:52:46
User entered 'Day 11'	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:38', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'cd385a35-3495-4237-82e1-1d9f9a3cb330' User entered 'No (N)'	System	03 Sep 2020 04:22:49
	System	03 Sep 2020 04:22:49

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-02T21:22:46', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'cd385a35-3495-4237-82e1-1d9f9a3cb330' User entered '02 Sep 2020 21:22'	System	03 Sep 2020 04:22:49
	System	03 Sep 2020 04:22:49

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 09:52:46

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	02 Sep 2020 11:40:10
User entered 'Day 12'	System	02 Sep 2020 11:40:10

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-03T19:55:06', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'dc847cf6-96b2-402d-b305-6d467f2ed368'	System	04 Sep 2020 02:55:11
User entered 'No (N)'	System	04 Sep 2020 02:55:11

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-03T19:55:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'dc847cf6-96b2-402d-b305-6d467f2ed368' User entered '03 Sep 2020 19:55'	System	04 Sep 2020 02:55:11
	System	04 Sep 2020 02:55:11

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 11:40:10

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 11:40:10

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	03 Sep 2020 04:22:16
User entered 'Day 13'	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-04T22:12:23', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eb50951-2b97-4759-8dda-263c18ba6e35'	System	05 Sep 2020 05:12:35
User entered 'No (N)'	System	05 Sep 2020 05:12:35

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-04T22:12:32', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eb50951-2b97-4759-8dda-263c18ba6e35'	System	05 Sep 2020 05:12:35
User entered '04 Sep 2020 22:12'	System	05 Sep 2020 05:12:35

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 04:22:16

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	04 Sep 2020 02:54:48
User entered 'Day 14'	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-05T17:23:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b7f66021-3978-4ad6-9b7d-e702061011a3' User entered 'No (N)'	System	06 Sep 2020 00:23:53
	System	06 Sep 2020 00:23:53

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-05T17:23:49', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b7f66021-3978-4ad6-9b7d-e702061011a3'	System	06 Sep 2020 00:23:53
User entered '05 Sep 2020 17:23'	System	06 Sep 2020 00:23:53

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 02:54:48

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	05 Sep 2020 05:12:12
User entered 'Day 15'	System	05 Sep 2020 05:12:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-06T18:44:06', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0d4e396c-4228-4d1c-8273-45171871d653'	System	07 Sep 2020 01:44:12
User entered 'No (N)'	System	07 Sep 2020 01:44:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-06T18:44:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0d4e396c-4228-4d1c-8273-45171871d653' User entered '06 Sep 2020 18:44'	System	07 Sep 2020 01:44:12
	System	07 Sep 2020 01:44:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 05:12:12

US3192345

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 05:12:12

US3192345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:20:43
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:03:48

US3192345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:20:43
User entered '02 Sep 2020'	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:03:48

US3192345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:20:43
User entered 'Contact Made (CONTACT MADE)'	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:03:48

US3192345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:20:43
User entered empty.	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:03:48

US3192345

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:21:41
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:03:55

US3192345

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	12 Sep 2020 21:03:55

US3192345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:09
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:04:49

US3192345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:09
User entered '07 Sep 2020'	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:04:49

US3192345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:09
User entered 'Contact Made (CONTACT MADE)'	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:04:49

US3192345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:50:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:09
User entered empty.	Norma Barrientos (b) (4) (b) (4)	12 Sep 2020 21:04:49

US3192345

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:47
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:50:35
User entered 'Yes (Y)'	(b) (4)	
	Norma Barrientos (b) (4)	12 Sep 2020 21:04:57
	(b) (4)	

US3192345

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	12 Sep 2020 21:04:57

US3192345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:36
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	17 Sep 2020 02:24:57

US3192345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:36
User entered '14 Sep 2020'	maggie Tono (b) (4) (b) (4)	17 Sep 2020 02:24:57

US3192345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:36
User entered 'Contact Made (CONTACT MADE)'	maggie Tono (b) (4) (b) (4)	17 Sep 2020 02:24:57

US3192345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:36
User entered empty.	maggie Tono (b) (4) (b) (4)	17 Sep 2020 02:24:57

US3192345

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:16
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	17 Sep 2020 02:25:03

US3192345

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	17 Sep 2020 02:25:03

US3192345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 07:54:47
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'sample was collected on V3 day' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:01:33
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:41:54
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:22:59
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:07

US3192345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:59
User entered '20 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:07

US3192345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:22:59
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:07

US3192345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'VISIT2'	System	20 Sep 2020 19:04:07

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User accepted default value 'Pre-Dose (PREDOSE)'	Saysamone Banks (b) (4)	20 Sep 2020 19:04:53
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '20 Sep 2020'	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '11:27'	(b) (4)	
	Saysamone Banks (b) (4)	20 Sep 2020 19:04:53
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '20 Sep 2020 11:27'	System	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '97.6' F	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered 'Oral (Oral)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	20 Sep 2020 19:04:53
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '66'	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'bpm'	System	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '12'	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'breaths/min'	System	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '158'	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:13
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '86'	(b) (4) Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	20 Sep 2020 19:04:53

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User closed query 'Please enter data. Thanks' (Site from CRA).		10 Oct 2020 22:51:43
Query 'Please enter data. Thanks' answered with 'updated ' (Site from CRA).	Norma Barrientos (b) (4)	05 Oct 2020 12:53:49
User entered 'Post-Dose (POSTDOSE)'	(b) (4)	
User entered 'Post-Dose (POSTDOSE)'	System	05 Oct 2020 12:53:30
User opened query 'Please enter data. Thanks' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 22:26:05

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered 'Yes (Y)'	(b) (4)	
	Norma Barrientos (b) (4)	05 Oct 2020 12:53:30
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '20 Sep 2020'	(b) (4)	
	Norma Barrientos (b) (4)	05 Oct 2020 12:53:30
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '12:28'	(b) (4)	
	Norma Barrientos (b) (4)	05 Oct 2020 12:53:30
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '20 Sep 2020 12:28'	System	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '97.8' F	(b) (4) Norma Barrientos (b) (4) (b) (4)	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered 'Oral (Oral)'	(b) (4) Norma Barrientos (b) (4) (b) (4)	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	05 Oct 2020 12:53:30
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '76'	(b) (4) Norma Barrientos (b) (4) (b) (4)	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'bpm'	System	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '18'	(b) (4) Norma Barrientos (b) (4) (b) (4)	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'breaths/min'	System	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '136'	(b) (4)	
	Norma Barrientos (b) (4)	05 Oct 2020 12:53:30
	(b) (4)	

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		17 Apr 2021 17:52:21
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
User entered '76'	(b) (4) Norma Barrientos (b) (4) (b) (4)	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	05 Oct 2020 12:53:30

US3192345

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:23:49
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:00

US3192345

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:23:49
User entered '20 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:00

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:24
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:24
User entered empty.	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:24
User entered empty.	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'MRNA-1273 OR PLACEBO'	System	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:24
User entered '20 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:24
User entered '11:55'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '20 Sep 2020 11:55'	System	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:24
User entered 'Left Arm (LEFT ARM)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
DataPoint Verified.		01 Oct 2020 22:27:24
User entered 'ONCE'	System	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'INTRAMUSCULAR'	System	20 Sep 2020 19:05:38

US3192345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:29
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:19

US3192345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:29
User entered '20 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:19

US3192345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:29
User entered '11:46'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:19

US3192345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '20 Sep 2020 11:46'	System	20 Sep 2020 19:06:19

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:34
User entered '20 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:31

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Saysamone Banks (b) (4)	20 Sep 2020 19:06:31

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:34
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:31

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:34
User entered '11:40'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:31

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '20 Sep 2020 11:40'	System	20 Sep 2020 19:06:31

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Saysamone Banks (b) (4)	20 Sep 2020 19:06:36

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:34
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:36

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:34
User entered empty.	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:36

US3192345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered empty.	System	20 Sep 2020 19:06:36

US3192345

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:37
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	20 Sep 2020 19:06:40

US3192345

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	20 Sep 2020 19:06:40

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:28:35', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd21c76fc-5331-4ec7-a141-9d71c98298ee' User entered 'Yes (Y)'	System	20 Sep 2020 19:28:55
	System	20 Sep 2020 19:28:55

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:28:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd21c76fc-5331-4ec7-a141-9d71c98298ee' User entered '97.8'	System	20 Sep 2020 19:28:55
	System	20 Sep 2020 19:28:55

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:28:48', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd21c76fc-5331-4ec7-a141-9d71c98298ee' User entered 'No (N)'	System	20 Sep 2020 19:28:55
	System	20 Sep 2020 19:28:55

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:28:52', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd21c76fc-5331-4ec7-a141-9d71c98298ee' User entered '20 Sep 2020 12:28'	System	20 Sep 2020 19:28:55
	System	20 Sep 2020 19:28:55

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 12:15'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 14:45'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 1, after vaccination (at home)'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:12:35', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '34e4aa4c-53ab-44b7-bb19-a0214e321d7e' User entered 'Yes (Y)'	System	21 Sep 2020 03:13:00
	System	21 Sep 2020 03:13:00

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:12:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '34e4aa4c-53ab-44b7-bb19-a0214e321d7e' User entered '98.9'	System	21 Sep 2020 03:13:00
	System	21 Sep 2020 03:13:00

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:12:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '34e4aa4c-53ab-44b7-bb19-a0214e321d7e' User entered 'Yes (Y)'	System	21 Sep 2020 03:13:00
	System	21 Sep 2020 03:13:00

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed with patient on what she took for fever 2 tabs 500mg each and then 4hours later took 1tab ibuprofen 800mg ' (Site from System).		29 Sep 2020 18:38:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:12:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '34e4aa4c-53ab-44b7-bb19-a0214e321d7e' User entered '1'	maggie Tono (b) (4) (b) (4)	24 Sep 2020 20:29:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	21 Sep 2020 03:13:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:12:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '34e4aa4c-53ab-44b7-bb19-a0214e321d7e' User entered '1'	System	21 Sep 2020 03:13:00
User entered '1'	System	21 Sep 2020 03:13:00

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:12:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '34e4aa4c-53ab-44b7-bb19-a0214e321d7e' User entered '0'	System	21 Sep 2020 03:13:00
	System	21 Sep 2020 03:13:00

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:12:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '34e4aa4c-53ab-44b7-bb19-a0214e321d7e' User entered '20 Sep 2020 20:12'	System	21 Sep 2020 03:13:00
	System	21 Sep 2020 03:13:00

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 15:40'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '21 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 2'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:05:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '867f3bf5-bb0c-418c-a131-c10d8238b49c' User entered 'Yes (Y)'	System	22 Sep 2020 01:06:34
	System	22 Sep 2020 01:06:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '867f3bf5-bb0c-418c-a131-c10d8238b49c' User entered '102.4'	System	22 Sep 2020 01:06:34
	System	22 Sep 2020 01:06:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:06', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '867f3bf5-bb0c-418c-a131-c10d8238b49c'	System	22 Sep 2020 01:06:34
User entered 'Yes (Y)'	System	22 Sep 2020 01:06:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed with patient on what she took for fever 2 tabs 500mg each and then 4hours later took 1tab ibuprofen 800mg ' (Site from System).		29 Sep 2020 18:39:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '867f3bf5-bb0c-418c-a131-c10d8238b49c' User entered '1'	maggie Tono (b) (4) (b) (4)	24 Sep 2020 20:29:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Sep 2020 01:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '867f3bf5-bb0c-418c-a131-c10d8238b49c' User entered '1'	System	22 Sep 2020 01:06:34
User entered '1'	System	22 Sep 2020 01:06:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '867f3bf5-bb0c-418c-a131-c10d8238b49c' User entered '0'	System	22 Sep 2020 01:06:34
	System	22 Sep 2020 01:06:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:32', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '867f3bf5-bb0c-418c-a131-c10d8238b49c'	System	22 Sep 2020 01:06:34
User entered '21 Sep 2020 18:06'	System	22 Sep 2020 01:06:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 3'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:37:49', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7c7a3cf7-b5a4-4c6c-bb65-b4625b9e39c0' User entered 'Yes (Y)'	System	23 Sep 2020 03:38:11
	System	23 Sep 2020 03:38:11

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:37:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7c7a3cf7-b5a4-4c6c-bb65-b4625b9e39c0' User entered '100.2'	System	23 Sep 2020 03:38:11
	System	23 Sep 2020 03:38:11

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:37:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7c7a3cf7-b5a4-4c6c-bb65-b4625b9e39c0'	System	23 Sep 2020 03:38:11
User entered 'Yes (Y)'	System	23 Sep 2020 03:38:11

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed with patient on what she took for fever 2 tabs 500mg each and then 4hours later took 1tab ibuprofen 800mg ' (Site from System).		29 Sep 2020 18:39:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	maggie Tono (b) (4)	24 Sep 2020 20:30:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7c7a3cf7-b5a4-4c6c-bb65-b4625b9e39c0'	System	23 Sep 2020 03:38:11
User entered '1'	System	23 Sep 2020 03:38:11

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7c7a3cf7-b5a4-4c6c-bb65-b4625b9e39c0' User entered '0'	System	23 Sep 2020 03:38:11
	System	23 Sep 2020 03:38:11

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7c7a3cf7-b5a4-4c6c-bb65-b4625b9e39c0' User entered '22 Sep 2020 20:38'	System	23 Sep 2020 03:38:11
	System	23 Sep 2020 03:38:11

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 4'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:06', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0c960c32-ab5b-4051-b562-30b5e5edf2a3' User entered 'Yes (Y)'	System	24 Sep 2020 04:38:34
	System	24 Sep 2020 04:38:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0c960c32-ab5b-4051-b562-30b5e5edf2a3' User entered '98.4'	System	24 Sep 2020 04:38:34
	System	24 Sep 2020 04:38:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0c960c32-ab5b-4051-b562-30b5e5edf2a3'	System	24 Sep 2020 04:38:34
User entered 'No (N)'	System	24 Sep 2020 04:38:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:31', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0c960c32-ab5b-4051-b562-30b5e5edf2a3' User entered '23 Sep 2020 21:38'	System	24 Sep 2020 04:38:34
	System	24 Sep 2020 04:38:34

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 5'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T22:59:49', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f2946c51-3d8a-4b46-a376-db19355572bf' User entered 'Yes (Y)'	System	25 Sep 2020 06:00:07
	System	25 Sep 2020 06:00:07

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T22:59:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f2946c51-3d8a-4b46-a376-db19355572bf' User entered '98.5'	System	25 Sep 2020 06:00:07
	System	25 Sep 2020 06:00:07

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T22:59:59', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f2946c51-3d8a-4b46-a376-db19355572bf' User entered 'No (N)'	System	25 Sep 2020 06:00:07
	System	25 Sep 2020 06:00:07

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f2946c51-3d8a-4b46-a376-db19355572bf' User entered '24 Sep 2020 23:00'	System	25 Sep 2020 06:00:07
	System	25 Sep 2020 06:00:07

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 6'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:13', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f76f951c-c984-4c04-83c7-fca4ed50883a' User entered 'Yes (Y)'	System	26 Sep 2020 04:21:32
	System	26 Sep 2020 04:21:32

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:22', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f76f951c-c984-4c04-83c7-fca4ed50883a' User entered '98.0'	System	26 Sep 2020 04:21:32
	System	26 Sep 2020 04:21:32

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f76f951c-c984-4c04-83c7-fca4ed50883a' User entered 'No (N)'	System	26 Sep 2020 04:21:32
	System	26 Sep 2020 04:21:32

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:27', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'f76f951c-c984-4c04-83c7-fca4ed50883a' User entered '25 Sep 2020 21:21'	System	26 Sep 2020 04:21:32
	System	26 Sep 2020 04:21:32

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 7'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:01:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9907e900-8f50-4461-8409-5b0ce4fb1919' User entered 'Yes (Y)'	System	27 Sep 2020 05:02:09
	System	27 Sep 2020 05:02:09

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:01:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9907e900-8f50-4461-8409-5b0ce4fb1919' User entered '97.7'	System	27 Sep 2020 05:02:09
	System	27 Sep 2020 05:02:09

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:03', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9907e900-8f50-4461-8409-5b0ce4fb1919'	System	27 Sep 2020 05:02:09
User entered 'No (N)'	System	27 Sep 2020 05:02:09

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '9907e900-8f50-4461-8409-5b0ce4fb1919' User entered '26 Sep 2020 22:02'	System	27 Sep 2020 05:02:09
	System	27 Sep 2020 05:02:09

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:28:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a8f68fb9-15c6-41c9-a487-24d98262ecf0'	System	20 Sep 2020 19:29:14
User entered 'None (1)'	System	20 Sep 2020 19:29:14

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a8f68fb9-15c6-41c9-a487-24d98262ecf0'	System	20 Sep 2020 19:29:14
User entered 'No (N)'	System	20 Sep 2020 19:29:14

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a8f68fb9-15c6-41c9-a487-24d98262ecf0'	System	20 Sep 2020 19:29:14
User entered 'No (N)'	System	20 Sep 2020 19:29:14

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a8f68fb9-15c6-41c9-a487-24d98262ecf0'	System	20 Sep 2020 19:29:14
User entered 'None (1)'	System	20 Sep 2020 19:29:14

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a8f68fb9-15c6-41c9-a487-24d98262ecf0' User entered '20 Sep 2020 12:29'	System	20 Sep 2020 19:29:14
	System	20 Sep 2020 19:29:14

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 12:15'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 14:45'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 1, after vaccination (at home)'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:13:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eaefe4c-82a7-4bf0-92f3-3be56d3f023d' User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 03:18:44
	System	21 Sep 2020 03:18:44

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:13:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eaefe4c-82a7-4bf0-92f3-3be56d3f023d' User entered 'No (N)'	System	21 Sep 2020 03:18:44
	System	21 Sep 2020 03:18:44

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:14:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eaefe4c-82a7-4bf0-92f3-3be56d3f023d' User entered 'Yes (Y)'	System	21 Sep 2020 03:18:44
	System	21 Sep 2020 03:18:44

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:20', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eaefe4c-82a7-4bf0-92f3-3be56d3f023d' User entered '1'	System	21 Sep 2020 03:18:44
	System	21 Sep 2020 03:18:44

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eaefe4c-82a7-4bf0-92f3-3be56d3f023d' User entered 'None (1)'	System	21 Sep 2020 03:18:44
	System	21 Sep 2020 03:18:44

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:38', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '0eaefe4c-82a7-4bf0-92f3-3be56d3f023d' User entered '20 Sep 2020 20:18'	System	21 Sep 2020 03:18:44
	System	21 Sep 2020 03:18:44

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 15:40'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '21 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 2'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:43', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '58008028-1398-4412-9d04-ddc25afa687b'	System	22 Sep 2020 01:07:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Sep 2020 01:07:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:06:48', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '58008028-1398-4412-9d04-ddc25afa687b'	System	22 Sep 2020 01:07:59
User entered 'Yes (Y)'	System	22 Sep 2020 01:07:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:07:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '58008028-1398-4412-9d04-ddc25afa687b' User entered '2'	System	22 Sep 2020 01:07:59
	System	22 Sep 2020 01:07:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:07:15', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '58008028-1398-4412-9d04-ddc25afa687b' User entered 'Yes (Y)'	System	22 Sep 2020 01:07:59
	System	22 Sep 2020 01:07:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:07:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '58008028-1398-4412-9d04-ddc25afa687b' User entered '2'	System	22 Sep 2020 01:07:59
	System	22 Sep 2020 01:07:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:07:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '58008028-1398-4412-9d04-ddc25afa687b'	System	22 Sep 2020 01:07:59
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 01:07:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:07:56', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '58008028-1398-4412-9d04-ddc25afa687b' User entered '21 Sep 2020 18:07'	System	22 Sep 2020 01:07:59
	System	22 Sep 2020 01:07:59

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 3'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eea4a756-4389-4da5-95b6-3d508269bea5'	System	23 Sep 2020 03:38:37
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 03:38:37

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:13', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eea4a756-4389-4da5-95b6-3d508269bea5' User entered 'No (N)'	System	23 Sep 2020 03:38:37
	System	23 Sep 2020 03:38:37

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:17', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eea4a756-4389-4da5-95b6-3d508269bea5' User entered 'Yes (Y)'	System	23 Sep 2020 03:38:37
	System	23 Sep 2020 03:38:37

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:20', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eea4a756-4389-4da5-95b6-3d508269bea5' User entered '3'	System	23 Sep 2020 03:38:37
	System	23 Sep 2020 03:38:37

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eea4a756-4389-4da5-95b6-3d508269bea5'	System	23 Sep 2020 03:38:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	23 Sep 2020 03:38:37

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:31', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'eea4a756-4389-4da5-95b6-3d508269bea5' User entered '22 Sep 2020 20:38'	System	23 Sep 2020 03:38:37
	System	23 Sep 2020 03:38:37

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 4'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:42', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '201ab166-7da5-4292-8084-224b434efbc9'	System	24 Sep 2020 04:39:22
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 04:39:22

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '201ab166-7da5-4292-8084-224b434efbc9' User entered 'No (N)'	System	24 Sep 2020 04:39:22
	System	24 Sep 2020 04:39:22

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:52', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '201ab166-7da5-4292-8084-224b434efbc9' User entered 'Yes (Y)'	System	24 Sep 2020 04:39:22
	System	24 Sep 2020 04:39:22

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:38:56', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '201ab166-7da5-4292-8084-224b434efbc9' User entered '2'	System	24 Sep 2020 04:39:22
	System	24 Sep 2020 04:39:22

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:15', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '201ab166-7da5-4292-8084-224b434efbc9'	System	24 Sep 2020 04:39:22
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 04:39:22

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:20', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '201ab166-7da5-4292-8084-224b434efbc9' User entered '23 Sep 2020 21:39'	System	24 Sep 2020 04:39:22
	System	24 Sep 2020 04:39:22

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 5'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:05', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '06b2d077-805a-4230-89ba-94144055b7e8'	System	25 Sep 2020 06:00:39
User entered 'None (1)'	System	25 Sep 2020 06:00:39

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:16', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '06b2d077-805a-4230-89ba-94144055b7e8' User entered 'No (N)'	System	25 Sep 2020 06:00:39
	System	25 Sep 2020 06:00:39

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '06b2d077-805a-4230-89ba-94144055b7e8' User entered 'Yes (Y)'	System	25 Sep 2020 06:00:39
	System	25 Sep 2020 06:00:39

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '06b2d077-805a-4230-89ba-94144055b7e8' User entered '1'	System	25 Sep 2020 06:00:39
	System	25 Sep 2020 06:00:39

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:31', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '06b2d077-805a-4230-89ba-94144055b7e8'	System	25 Sep 2020 06:00:39
User entered 'None (1)'	System	25 Sep 2020 06:00:39

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:33', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '06b2d077-805a-4230-89ba-94144055b7e8' User entered '24 Sep 2020 23:00'	System	25 Sep 2020 06:00:39
	System	25 Sep 2020 06:00:39

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 6'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:31', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd97428ed-a19d-4b25-8bf9-0649736756cc'	System	26 Sep 2020 04:21:46
User entered 'None (1)'	System	26 Sep 2020 04:21:46

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:33', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd97428ed-a19d-4b25-8bf9-0649736756cc' User entered 'No (N)'	System	26 Sep 2020 04:21:46
	System	26 Sep 2020 04:21:46

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:36', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd97428ed-a19d-4b25-8bf9-0649736756cc' User entered 'No (N)'	System	26 Sep 2020 04:21:46
	System	26 Sep 2020 04:21:46

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd97428ed-a19d-4b25-8bf9-0649736756cc' User entered 'None (1)'	System	26 Sep 2020 04:21:46
	System	26 Sep 2020 04:21:46

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd97428ed-a19d-4b25-8bf9-0649736756cc' User entered '25 Sep 2020 21:21'	System	26 Sep 2020 04:21:46
	System	26 Sep 2020 04:21:46

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 7'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1d7dae98-f637-47d9-93f6-9c9822c7bd3f' User entered 'None (1)'	System	27 Sep 2020 05:02:23
	System	27 Sep 2020 05:02:23

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1d7dae98-f637-47d9-93f6-9c9822c7bd3f' User entered 'No (N)'	System	27 Sep 2020 05:02:23
	System	27 Sep 2020 05:02:23

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:16', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1d7dae98-f637-47d9-93f6-9c9822c7bd3f' User entered 'No (N)'	System	27 Sep 2020 05:02:23
	System	27 Sep 2020 05:02:23

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1d7dae98-f637-47d9-93f6-9c9822c7bd3f' User entered 'None (1)'	System	27 Sep 2020 05:02:23
	System	27 Sep 2020 05:02:23

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:21', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1d7dae98-f637-47d9-93f6-9c9822c7bd3f' User entered '26 Sep 2020 22:02'	System	27 Sep 2020 05:02:23
	System	27 Sep 2020 05:02:23

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072' User entered 'None (0)'	System	20 Sep 2020 19:29:42
	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:17', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072' User entered 'None (0)'	System	20 Sep 2020 19:29:42
	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:21', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072' User entered 'None (0)'	System	20 Sep 2020 19:29:42
	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072' User entered 'None (0)'	System	20 Sep 2020 19:29:42
	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:27', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072' User entered 'None (0)'	System	20 Sep 2020 19:29:42
	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072' User entered 'None (0)'	System	20 Sep 2020 19:29:42
	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:33', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072'	System	20 Sep 2020 19:29:42
User entered 'No (N)'	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T12:29:37', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd5ba32a3-252f-4020-9f7d-626483817072'	System	20 Sep 2020 19:29:42
User entered '20 Sep 2020 12:29'	System	20 Sep 2020 19:29:42

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 12:15'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 14:45'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 1, after vaccination (at home)'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:42', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050' User entered 'None (0)'	System	21 Sep 2020 03:19:09
	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:48', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050' User entered 'None (0)'	System	21 Sep 2020 03:19:09
	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:52', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050'	System	21 Sep 2020 03:19:09
User entered 'Some interference with activity (2)'	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050'	System	21 Sep 2020 03:19:09
User entered 'No interference with activity (1)'	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:18:59', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050' User entered 'None (0)'	System	21 Sep 2020 03:19:09
	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:19:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050' User entered 'None (0)'	System	21 Sep 2020 03:19:09
	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:19:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050' User entered 'No (N)'	System	21 Sep 2020 03:19:09
	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-20T20:19:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '4e618fc2-e256-4636-9f0b-a5ba01837050' User entered '20 Sep 2020 20:19'	System	21 Sep 2020 03:19:09
	System	21 Sep 2020 03:19:09

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '20 Sep 2020 15:40'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '21 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 2'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:04', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe'	System	22 Sep 2020 01:08:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe'	System	22 Sep 2020 01:08:55
User entered 'Some interference with activity (2)'	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:16', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe'	System	22 Sep 2020 01:08:55
User entered 'Significant; prevents daily activity (3)'	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:20', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe' User entered 'Significant; prevents daily activity (3)'	System	22 Sep 2020 01:08:55
	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe'	System	22 Sep 2020 01:08:55
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:30', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe'	System	22 Sep 2020 01:08:55
User entered 'Some interference with activity not requiring medical attention (2)'	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:40', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe' User entered 'No (N)'	System	22 Sep 2020 01:08:55
	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-21T18:08:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'de83e19d-c315-4090-8779-51fee9d797fe' User entered '21 Sep 2020 18:08'	System	22 Sep 2020 01:08:55
	System	22 Sep 2020 01:08:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 3'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:37', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547'	System	23 Sep 2020 03:39:15
User entered 'No interference with activity (1)'	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:44', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547'	System	23 Sep 2020 03:39:15
User entered 'Some interference with activity (2)'	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547'	System	23 Sep 2020 03:39:15
User entered 'Some interference with activity (2)'	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547'	System	23 Sep 2020 03:39:15
User entered 'Some interference with activity (2)'	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:38:56', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547'	System	23 Sep 2020 03:39:15
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:39:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547'	System	23 Sep 2020 03:39:15
User entered 'No interference with activity (1)'	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:39:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547' User entered 'No (N)'	System	23 Sep 2020 03:39:15
	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-22T20:39:10', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ed08aec8-4778-41ba-b30e-3cfef8df6547'	System	23 Sep 2020 03:39:15
User entered '22 Sep 2020 20:39'	System	23 Sep 2020 03:39:15

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 4'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214' User entered 'None (0)'	System	24 Sep 2020 04:40:04
	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:32', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214' User entered 'None (0)'	System	24 Sep 2020 04:40:04
	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214'	System	24 Sep 2020 04:40:04
User entered 'No interference with activity (1)'	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:43', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214' User entered 'None (0)'	System	24 Sep 2020 04:40:04
	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214' User entered 'None (0)'	System	24 Sep 2020 04:40:04
	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214' User entered 'None (0)'	System	24 Sep 2020 04:40:04
	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:39:56', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214'	System	24 Sep 2020 04:40:04
User entered 'No (N)'	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-23T21:40:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'fd1aa9e7-e01f-455f-8e8c-cfa97425d214'	System	24 Sep 2020 04:40:04
User entered '23 Sep 2020 21:40'	System	24 Sep 2020 04:40:04

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '23 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 5'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:37', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered 'None (0)'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered 'None (0)'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:42', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered 'None (0)'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:43', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered 'None (0)'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:45', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered 'None (0)'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:47', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered 'None (0)'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered 'No (N)'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-24T23:00:52', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b6664c9f-472c-43d0-91d9-1d0bab401ace' User entered '24 Sep 2020 23:00'	System	25 Sep 2020 06:00:55
	System	25 Sep 2020 06:00:55

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '24 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 6'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:46', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccb4'	System	26 Sep 2020 04:22:00
User entered 'None (0)'	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:48', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccb4'	System	26 Sep 2020 04:22:00
User entered 'None (0)'	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccb4'	System	26 Sep 2020 04:22:00
User entered 'None (0)'	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:52', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccb4'	System	26 Sep 2020 04:22:00
User entered 'None (0)'	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:53', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccb4'	System	26 Sep 2020 04:22:00
User entered 'None (0)'	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:55', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccb4'	System	26 Sep 2020 04:22:00
User entered 'None (0)'	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:57', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccb4'	System	26 Sep 2020 04:22:00
User entered 'No (N)'	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-25T21:21:58', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '052a95a1-cc20-4ce2-b402-20ec43ccbhc4' User entered '25 Sep 2020 21:21'	System	26 Sep 2020 04:22:00
	System	26 Sep 2020 04:22:00

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '25 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	20 Sep 2020 19:05:38
User entered 'Day 7'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered 'None (0)'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered 'None (0)'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered 'None (0)'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered 'None (0)'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:30', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered 'None (0)'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered 'None (0)'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:38', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered 'No (N)'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-09-26T22:02:40', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'e151116a-1e3c-4143-a3e4-21d861cea5cd' User entered '26 Sep 2020 22:02'	System	27 Sep 2020 05:02:43
	System	27 Sep 2020 05:02:43

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '26 Sep 2020 12:00'	System	20 Sep 2020 19:05:38

US3192345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
User entered '27 Sep 2020 11:59'	System	20 Sep 2020 19:05:38

US3192345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:46
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	29 Sep 2020 19:33:25

US3192345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:46
User entered '28 Sep 2020'	Zoe Sesma (b) (4) (b) (4)	29 Sep 2020 19:33:25

US3192345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:46
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4) (b) (4)	29 Sep 2020 19:33:25

US3192345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:46
User entered empty.	Zoe Sesma (b) (4) (b) (4)	29 Sep 2020 19:33:25

US3192345

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:27:49
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	29 Sep 2020 19:33:13

US3192345

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	29 Sep 2020 19:33:13

US3192345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:17
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:12:49

US3192345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:17
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Nov 2020 23:13:07
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	18 Nov 2020 23:13:07
User entered '05 Oct 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:13:07
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Nov 2020 23:12:49
User entered '05 Nov 2020'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:12:49

US3192345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:17
User entered 'Contact Made (CONTACT MADE)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:12:49

US3192345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:17
User entered empty.	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:12:49

US3192345

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:20
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:10:19

US3192345

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	18 Nov 2020 23:10:19

US3192345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:31
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:13:27

US3192345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:31
User entered '14 Oct 2020'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:13:27

US3192345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:31
User entered 'Contact Made (CONTACT MADE)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:13:27

US3192345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:31
User entered empty.	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:13:27

US3192345

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:20:33
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:13:32

US3192345

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	18 Nov 2020 23:13:32

US3192345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:06
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:14:48

US3192345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:06
User entered '22 Oct 2020'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:14:48

US3192345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:06
User entered 'Clinic (Clinic)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:14:48

US3192345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'VISIT3'	System	18 Nov 2020 23:14:48

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered '22 Oct 2020'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered '15:25'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '22 Oct 2020 15:25'	System	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered '97.6' F	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered 'Oral (Oral)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered empty.	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered '74'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'bpm'	System	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered '16'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'breaths/min'	System	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered '125'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:15
User entered '74'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'mmHg'	System	18 Nov 2020 23:16:43

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50

US3192345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50

US3192345

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:21
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:15:24

US3192345

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:21
User entered '22 Oct 2020'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:15:24

US3192345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:28
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:15:14

US3192345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:28
User entered '22 Oct 2020'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:15:14

US3192345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:28
User entered '15:35'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:15:14

US3192345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered '22 Oct 2020 15:35'	System	18 Nov 2020 23:15:14

US3192345

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:44:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:31
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	18 Nov 2020 23:14:53

US3192345

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	18 Nov 2020 23:14:53

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 64'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-10-27T12:00:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b42ecc60-543c-47a9-8923-822aff591fd3'	System	27 Oct 2020 18:00:16
User entered 'No (N)'	System	27 Oct 2020 18:00:16

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-10-27T12:00:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b42ecc60-543c-47a9-8923-822aff591fd3'	System	27 Oct 2020 18:00:16
User entered 'No (N)'	System	27 Oct 2020 18:00:16

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-10-27T12:00:13', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'b42ecc60-543c-47a9-8923-822aff591fd3' User entered '27 Oct 2020 12:00:13'	System	27 Oct 2020 18:00:16
	System	27 Oct 2020 18:00:16

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered '23 Oct 2020 00:01'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered '27 Oct 2020 23:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 71'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-10-30T10:56:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2be058ca-e096-46da-a788-dabbe62cdf0d'	System	30 Oct 2020 17:57:01
User entered 'No (N)'	System	30 Oct 2020 17:57:01

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-10-30T10:56:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2be058ca-e096-46da-a788-dabbe62cdf0d'	System	30 Oct 2020 17:57:01
User entered 'Yes (Y)'	System	30 Oct 2020 17:57:01

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Please 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)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-10-30T10:56:48', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2be058ca-e096-46da-a788-dabbe62cdf0d'	System	30 Oct 2020 17:57:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Oct 2020 17:57:01

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-10-30T10:56:51', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2be058ca-e096-46da-a788-dabbe62cdf0d' User entered '30 Oct 2020 10:56:51'	System	30 Oct 2020 17:57:01
	System	30 Oct 2020 17:57:01

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered '30 Oct 2020 00:01'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered '03 Nov 2020 23:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered 'Day 78'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-11-09T23:12:22', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6a5639dc-d840-4a3c-9baf-4f303ac27fb7'	System	10 Nov 2020 06:12:37
User entered 'No (N)'	System	10 Nov 2020 06:12:37

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-11-09T23:12:29', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6a5639dc-d840-4a3c-9baf-4f303ac27fb7'	System	10 Nov 2020 06:12:37
User entered 'No (N)'	System	10 Nov 2020 06:12:37

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-11-09T23:12:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6a5639dc-d840-4a3c-9baf-4f303ac27fb7' User entered '09 Nov 2020 23:12:34'	System	10 Nov 2020 06:12:37
	System	10 Nov 2020 06:12:37

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered '06 Nov 2020 00:01'	System	23 Aug 2020 22:15:35

US3192345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:30
Data entry locked.	System	23 Aug 2020 22:15:35
User entered '10 Nov 2020 23:59'	System	23 Aug 2020 22:15:35

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-11-24T06:45:50', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7f6b5ff0-7ec7-421b-a80d-58b6068b309a'	System	24 Nov 2020 13:46:29
User entered 'No (N)'	System	24 Nov 2020 13:46:29

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-11-24T06:46:01', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7f6b5ff0-7ec7-421b-a80d-58b6068b309a' User entered 'Yes (Y)'	System	24 Nov 2020 13:46:29
	System	24 Nov 2020 13:46:29

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-11-24T06:46:13', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7f6b5ff0-7ec7-421b-a80d-58b6068b309a'	System	24 Nov 2020 13:46:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 13:46:29

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-11-24T06:46:20', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '7f6b5ff0-7ec7-421b-a80d-58b6068b309a' User entered '24 Nov 2020 06:46:20'	System	24 Nov 2020 13:46:29
	System	24 Nov 2020 13:46:29

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-01T07:19:03', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2f843cd-987f-4a7e-a163-9c18794c5b36'	System	01 Dec 2020 14:19:15
User entered 'No (N)'	System	01 Dec 2020 14:19:15

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-01T07:19:07', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2f843cd-987f-4a7e-a163-9c18794c5b36'	System	01 Dec 2020 14:19:15
User entered 'No (N)'	System	01 Dec 2020 14:19:15

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-01T07:19:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'd2f843cd-987f-4a7e-a163-9c18794c5b36'	System	01 Dec 2020 14:19:15
User entered '01 Dec 2020 07:19:11'	System	01 Dec 2020 14:19:15

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-08T00:01:16', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bfe6fa32-b9b6-47d0-a1b1-23627b365b06'	System	08 Dec 2020 07:01:29
User entered 'No (N)'	System	08 Dec 2020 07:01:29

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-08T00:01:22', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bfe6fa32-b9b6-47d0-a1b1-23627b365b06'	System	08 Dec 2020 07:01:29
User entered 'No (N)'	System	08 Dec 2020 07:01:29

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-08T00:01:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bfe6fa32-b9b6-47d0-a1b1-23627b365b06' User entered '08 Dec 2020 00:01:26'	System	08 Dec 2020 07:01:29
	System	08 Dec 2020 07:01:29

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-17T15:18:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bca727f7-1841-4033-ad3b-88c368398a6c' User entered 'No (N)'	System	17 Dec 2020 22:18:37
	System	17 Dec 2020 22:18:37

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-17T15:18:21', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bca727f7-1841-4033-ad3b-88c368398a6c' User entered 'Yes (Y)'	System	17 Dec 2020 22:18:37
	System	17 Dec 2020 22:18:37

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-17T15:18:24', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bca727f7-1841-4033-ad3b-88c368398a6c'	System	17 Dec 2020 22:18:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 22:18:37

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-17T15:18:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bca727f7-1841-4033-ad3b-88c368398a6c' User entered '17 Dec 2020 15:18:28'	System	17 Dec 2020 22:18:37
	System	17 Dec 2020 22:18:37

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-24T12:10:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f69b130-2e3b-41bc-aaa9-92ec25549887' User entered 'No (N)'	System	24 Dec 2020 20:10:18
	System	24 Dec 2020 20:10:18

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-24T12:10:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f69b130-2e3b-41bc-aaa9-92ec25549887'	System	24 Dec 2020 20:10:18
User entered 'No (N)'	System	24 Dec 2020 20:10:18

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-24T12:10:15', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '1f69b130-2e3b-41bc-aaa9-92ec25549887' User entered '24 Dec 2020 12:10:15'	System	24 Dec 2020 20:10:18
	System	24 Dec 2020 20:10:18

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-31T22:34:19', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2fac5d61-1171-406a-9374-a9740ba2d15e' User entered 'No (N)'	System	01 Jan 2021 05:34:31
	System	01 Jan 2021 05:34:31

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-31T22:34:22', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2fac5d61-1171-406a-9374-a9740ba2d15e'	System	01 Jan 2021 05:34:31
User entered 'No (N)'	System	01 Jan 2021 05:34:31

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2020-12-31T22:34:26', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '2fac5d61-1171-406a-9374-a9740ba2d15e' User entered '31 Dec 2020 22:34:26'	System	01 Jan 2021 05:34:31
	System	01 Jan 2021 05:34:31

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-05T17:54:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '71e2f287-fd7d-4763-8d75-890d0b11774a'	System	06 Jan 2021 00:54:24
User entered 'No (N)'	System	06 Jan 2021 00:54:24

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-05T17:54:19', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '71e2f287-fd7d-4763-8d75-890d0b11774a'	System	06 Jan 2021 00:54:24
User entered 'No (N)'	System	06 Jan 2021 00:54:24

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-05T17:54:22', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '71e2f287-fd7d-4763-8d75-890d0b11774a' User entered '05 Jan 2021 17:54:22'	System	06 Jan 2021 00:54:24
	System	06 Jan 2021 00:54:24

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-12T07:26:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '056af54f-8178-4550-aa31-534a70639646'	System	12 Jan 2021 14:26:07
User entered 'No (N)'	System	12 Jan 2021 14:26:07

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-12T07:26:02', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '056af54f-8178-4550-aa31-534a70639646'	System	12 Jan 2021 14:26:07
User entered 'No (N)'	System	12 Jan 2021 14:26:07

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-12T07:26:05', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '056af54f-8178-4550-aa31-534a70639646' User entered '12 Jan 2021 07:26:05'	System	12 Jan 2021 14:26:07
	System	12 Jan 2021 14:26:07

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-21T17:41:11', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '564784c9-7e49-477c-bc12-25c8ff5fbeat'	System	22 Jan 2021 00:41:23
User entered 'No (N)'	System	22 Jan 2021 00:41:23

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-21T17:41:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '564784c9-7e49-477c-bc12-25c8ff5fbeat'	System	22 Jan 2021 00:41:23
User entered 'No (N)'	System	22 Jan 2021 00:41:23

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-21T17:41:18', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '564784c9-7e49-477c-bc12-25c8ff5fbeat'	System	22 Jan 2021 00:41:23
User entered '21 Jan 2021 17:41:18'	System	22 Jan 2021 00:41:23

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-26T13:22:34', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '167414b3-b6c7-4d3b-94ed-3904974e2d78'	System	26 Jan 2021 21:11:45
User entered 'No (N)'	System	26 Jan 2021 21:11:45

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-26T13:22:36', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '167414b3-b6c7-4d3b-94ed-3904974e2d78'	System	26 Jan 2021 21:11:45
User entered 'No (N)'	System	26 Jan 2021 21:11:45

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-01-26T13:22:39', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '167414b3-b6c7-4d3b-94ed-3904974e2d78'	System	26 Jan 2021 21:11:45
User entered '26 Jan 2021 13:22:39'	System	26 Jan 2021 21:11:45

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-02T00:04:23', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '5ba2bb75-6082-46e5-8630-d986b3879570' User entered 'No (N)'	System	02 Feb 2021 07:04:33
	System	02 Feb 2021 07:04:33

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-02T00:04:25', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '5ba2bb75-6082-46e5-8630-d986b3879570'	System	02 Feb 2021 07:04:33
User entered 'No (N)'	System	02 Feb 2021 07:04:33

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-02T00:04:28', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '5ba2bb75-6082-46e5-8630-d986b3879570' User entered '02 Feb 2021 00:04:28'	System	02 Feb 2021 07:04:33
	System	02 Feb 2021 07:04:33

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-11T13:37:08', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '343b7136-bd8a-4090-8d9a-3ac80ba13af4' User entered 'No (N)'	System	11 Feb 2021 20:37:19
	System	11 Feb 2021 20:37:19

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-11T13:37:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '343b7136-bd8a-4090-8d9a-3ac80ba13af4'	System	11 Feb 2021 20:37:19
User entered 'No (N)'	System	11 Feb 2021 20:37:19

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-11T13:37:14', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '343b7136-bd8a-4090-8d9a-3ac80ba13af4' User entered '11 Feb 2021 13:37:14'	System	11 Feb 2021 20:37:19
	System	11 Feb 2021 20:37:19

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-16T22:37:41', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bcae6253-4ace-4204-bc83-352c38c90f0c' User entered 'No (N)'	System	17 Feb 2021 05:37:49
	System	17 Feb 2021 05:37:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-16T22:37:43', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bcae6253-4ace-4204-bc83-352c38c90f0c'	System	17 Feb 2021 05:37:49
User entered 'No (N)'	System	17 Feb 2021 05:37:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-16T22:37:46', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bcae6253-4ace-4204-bc83-352c38c90f0c' User entered '16 Feb 2021 22:37:46'	System	17 Feb 2021 05:37:49
	System	17 Feb 2021 05:37:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-23T00:04:12', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '141d660a-a4aa-40a6-963c-3d9fd0517c7e'	System	02 Mar 2021 13:05:34
User entered 'No (N)'	System	02 Mar 2021 13:05:34

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-23T00:04:13', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '141d660a-a4aa-40a6-963c-3d9fd0517c7e'	System	02 Mar 2021 13:05:34
User entered 'No (N)'	System	02 Mar 2021 13:05:34

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-02-23T00:04:16', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '141d660a-a4aa-40a6-963c-3d9fd0517c7e' User entered '23 Feb 2021 00:04:16'	System	02 Mar 2021 13:05:34
	System	02 Mar 2021 13:05:34

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-02T06:05:37-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c0f99799-53b5-4495-a39a-b937117b37cc'	System	07 Mar 2021 05:24:18
User entered 'No (N)'	System	07 Mar 2021 05:24:18

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-02T06:05:44-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c0f99799-53b5-4495-a39a-b937117b37cc'	System	07 Mar 2021 05:24:18
User entered 'No (N)'	System	07 Mar 2021 05:24:18

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-02T06:05:48-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'c0f99799-53b5-4495-a39a-b937117b37cc'	System	07 Mar 2021 05:24:18
User entered '02 Mar 2021 06:05:48'	System	07 Mar 2021 05:24:18

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-09T16:49:53-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ba69c815-9f8d-4038-aaa8-09ead61ae590'	System	09 Mar 2021 23:50:05
User entered 'No (N)'	System	09 Mar 2021 23:50:05

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-09T16:49:55-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ba69c815-9f8d-4038-aaa8-09ead61ae590'	System	09 Mar 2021 23:50:05
User entered 'No (N)'	System	09 Mar 2021 23:50:05

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-09T16:50:00-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'ba69c815-9f8d-4038-aaa8-09ead61ae590'	System	09 Mar 2021 23:50:05
User entered '09 Mar 2021 16:50:00'	System	09 Mar 2021 23:50:05

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-17T19:02:52-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6d8fc92e-62f8-406e-ab29-e0a3c1c4ba4a'	System	18 Mar 2021 02:06:19
User entered 'No (N)'	System	18 Mar 2021 02:06:19

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-17T19:02:54-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6d8fc92e-62f8-406e-ab29-e0a3c1c4ba4a'	System	18 Mar 2021 02:06:19
User entered 'No (N)'	System	18 Mar 2021 02:06:19

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-17T19:02:57-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '6d8fc92e-62f8-406e-ab29-e0a3c1c4ba4a' User entered '17 Mar 2021 19:02:57'	System	18 Mar 2021 02:06:19
	System	18 Mar 2021 02:06:19

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-23T07:36:21-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '405fc69a-b1c1-48c1-8367-2b63654b6125'	System	23 Mar 2021 14:36:37
User entered 'No (N)'	System	23 Mar 2021 14:36:37

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-23T07:36:22-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '405fc69a-b1c1-48c1-8367-2b63654b6125'	System	23 Mar 2021 14:36:37
User entered 'No (N)'	System	23 Mar 2021 14:36:37

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-23T07:36:25-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '405fc69a-b1c1-48c1-8367-2b63654b6125'	System	23 Mar 2021 14:36:37
User entered '23 Mar 2021 07:36:25'	System	23 Mar 2021 14:36:37

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-30T07:13:27-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '28e3ca39-97b8-44a2-823a-3995ce9603dc' User entered 'No (N)'	System	30 Mar 2021 14:14:13
	System	30 Mar 2021 14:14:13

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-30T07:13:29-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '28e3ca39-97b8-44a2-823a-3995ce9603dc'	System	30 Mar 2021 14:14:13
User entered 'No (N)'	System	30 Mar 2021 14:14:13

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-30T07:13:32-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '28e3ca39-97b8-44a2-823a-3995ce9603dc' User entered '30 Mar 2021 07:13:32'	System	30 Mar 2021 14:14:13
	System	30 Mar 2021 14:14:13

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-06T16:33:02-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bdc3796f-4739-49e5-97eb-6b99fda30a6c'	System	06 Apr 2021 23:33:11
User entered 'No (N)'	System	06 Apr 2021 23:33:11

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-06T16:33:05-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bdc3796f-4739-49e5-97eb-6b99fda30a6c'	System	06 Apr 2021 23:33:11
User entered 'No (N)'	System	06 Apr 2021 23:33:11

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-06T16:33:08-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'bdc3796f-4739-49e5-97eb-6b99fda30a6c'	System	06 Apr 2021 23:33:11
User entered '06 Apr 2021 16:33:08'	System	06 Apr 2021 23:33:11

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-13T06:46:25-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '8f000876-743d-422f-ac7e-dee71a8c6ff8'	System	13 Apr 2021 13:46:38
User entered 'No (N)'	System	13 Apr 2021 13:46:38

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-13T06:46:28-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '8f000876-743d-422f-ac7e-dee71a8c6ff8'	System	13 Apr 2021 13:46:38
User entered 'No (N)'	System	13 Apr 2021 13:46:38

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-13T06:46:33-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '8f000876-743d-422f-ac7e-dee71a8c6ff8'	System	13 Apr 2021 13:46:38
User entered '13 Apr 2021 06:46:33'	System	13 Apr 2021 13:46:38

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-20T13:33:32-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '07462c64-1413-4fd0-8d45-677d5734f53b'	System	20 Apr 2021 20:34:21
User entered 'No (N)'	System	20 Apr 2021 20:34:21

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-20T13:33:49-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '07462c64-1413-4fd0-8d45-677d5734f53b'	System	20 Apr 2021 20:34:21
User entered 'No (N)'	System	20 Apr 2021 20:34:21

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-20T13:34:17-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '07462c64-1413-4fd0-8d45-677d5734f53b'	System	20 Apr 2021 20:34:21
User entered '20 Apr 2021 13:34:17'	System	20 Apr 2021 20:34:21

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-27T16:15:23-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a54d9d35-f316-41a8-9893-a885b96212ed' User entered 'No (N)'	System	29 Apr 2021 00:11:16
	System	29 Apr 2021 00:11:16

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-27T16:15:26-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a54d9d35-f316-41a8-9893-a885b96212ed' User entered 'No (N)'	System	29 Apr 2021 00:11:16
	System	29 Apr 2021 00:11:16

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-04-27T16:15:29-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: 'a54d9d35-f316-41a8-9893-a885b96212ed' User entered '27 Apr 2021 16:15:29'	System	29 Apr 2021 00:11:16
	System	29 Apr 2021 00:11:16

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:57:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '18 Oct 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '22 Oct 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '25 Oct 2022 00:01'	System	19 Nov 2020 22:57:49

US3192345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:57:49
Amendment Manager: User entered '29 Oct 2022 23:59'	System	19 Nov 2020 22:57:49

US3192345

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 04:43:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-02T06:05:59-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '48c3e7ec-4152-45a6-bdb9-8d5e81ceee1e'	System	02 Mar 2021 13:06:27
User entered 'Yes (Y)'	System	02 Mar 2021 13:06:27

US3192345

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:58

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 04:43:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-02T06:06:08-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '48c3e7ec-4152-45a6-bdb9-8d5e81ceee1e' User entered 'No (N)'	System	02 Mar 2021 13:06:27
	System	02 Mar 2021 13:06:27

US3192345

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 04:43:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CA66CC4-5B5D-4788-8617-4381218F1034)', Time: '2021-03-02T06:06:17-07:00', User OID: 'PatientReportedOutcome (US3192345)', ODM File OID: '48c3e7ec-4152-45a6-bdb9-8d5e81ceee1e' User entered '02 Mar 2021 06:06:17'	System	02 Mar 2021 13:06:27
	System	02 Mar 2021 13:06:27

US3192345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:16:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:44
User entered 'Yes (Y)'		19 Nov 2020 00:18:55

US3192345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:16:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:44
User entered '18 Nov 2020'		19 Nov 2020 00:18:55

US3192345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:16:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:44
User entered 'Contact Made (CONTACT MADE)'		19 Nov 2020 00:18:55

US3192345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:16:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:44
User entered empty.		19 Nov 2020 00:18:55

US3192345

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:16:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:21:47
User entered 'Yes (Y)'		19 Nov 2020 00:18:59

US3192345

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:50
User entered 'I'	System	19 Nov 2020 00:18:59

US3192345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:14
User entered 'Yes (Y)'		17 Dec 2020 22:05:36

US3192345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:14
User entered '17 Dec 2020'		17 Dec 2020 22:05:36

US3192345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:14
User entered 'Contact Made (CONTACT MADE)'		17 Dec 2020 22:05:36

US3192345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:14
User entered empty.		17 Dec 2020 22:05:36

US3192345

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:17
User entered 'Yes (Y)'		17 Dec 2020 22:05:41

US3192345

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User entered 'I'	System	17 Dec 2020 22:05:41

US3192345

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 20:22:25
User entered 'Yes (Y)'		29 Jan 2021 01:23:51

US3192345

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:25
User entered '21 Jan 2021'		29 Jan 2021 01:23:51

US3192345

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:25
User entered 'Contact Made (CONTACT MADE)'		29 Jan 2021 01:23:51

US3192345

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:25
User entered empty.		29 Jan 2021 01:23:51

US3192345

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:22:28
User entered 'Yes (Y)'		29 Jan 2021 01:23:54

US3192345

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User entered 'I'	System	29 Jan 2021 01:23:54

US3192345

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
DataPoint Verified.		17 Apr 2021 17:58:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:20:01

US3192345

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
DataPoint Verified.		17 Apr 2021 17:58:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered '20 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:20:01

US3192345

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
DataPoint Verified.		17 Apr 2021 17:58:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:20:01

US3192345

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
DataPoint Verified.		17 Apr 2021 17:58:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:20:01

US3192345

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
DataPoint Verified.		17 Apr 2021 17:58:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:20:05

US3192345

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:10:09
User entered 'I'	System	23 Feb 2021 17:20:05

US3192345

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:58:30
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:03

US3192345

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:58:30
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:03

US3192345

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:58:30
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:03

US3192345

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered 'VISIT4'	System	24 Mar 2021 20:53:03

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '13:40'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered '24 Mar 2021 13:40'	System	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '65'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered 'bpm'	System	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered 'breaths/min'	System	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '120'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered 'mmHg'	System	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:10
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '80'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered 'mmHg'	System	02 Apr 2021 17:42:02

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56

US3192345

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56

US3192345

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:15
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:08

US3192345

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:15
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:08

US3192345

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:24

US3192345

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:24

US3192345

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '13:48'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:24

US3192345

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered '24 Mar 2021 13:48'	System	24 Mar 2021 20:53:24

US3192345

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
DataPoint Verified.		17 Apr 2021 17:59:51
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:29

US3192345

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:56
User entered 'I'	System	24 Mar 2021 20:53:29

US3192345

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:39
	(b) (4)	
User entered 'Yes (Y)'	Damaris Atondo (b) (4)	23 Apr 2021 17:11:46
	(b) (4)	

US3192345

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:39
User entered '20 Apr 2021'	(b) (4) Damaris Atondo (b) (4)	23 Apr 2021 17:11:46
	(b) (4)	

US3192345

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	23 Apr 2021 17:11:46

US3192345

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:39
User entered empty.	(b) (4) Damaris Atondo (b) (4)	23 Apr 2021 17:11:46
	(b) (4)	

US3192345

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:39
	(b) (4)	
User entered 'Yes (Y)'	Damaris Atondo (b) (4)	23 Apr 2021 17:11:51
	(b) (4)	

US3192345

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 17:11:51

US3192345

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:56:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:19:54

US3192345

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:56:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '1 Feb 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:19:54

US3192345

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:56:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Clinic (Clinic)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:19:54

US3192345

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 23:19:54

US3192345

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:39
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '1 Feb 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:15

US3192345

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:06:14

US3192345

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:39
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:15

US3192345

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:06:14

US3192345

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:39
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '1 Feb 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:15

US3192345

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:39
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:15

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:39
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:15

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:39
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:15

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:39
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'No (N)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:15

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
User entered empty.	System	01 Feb 2021 23:20:15

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:58

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
User entered empty.	System	01 Feb 2021 23:20:15

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:47
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:24

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:47
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '1 Feb 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:24

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:47
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '15:37'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:24

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
User entered '1 Feb 2021 15:37'	System	01 Feb 2021 23:20:24

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:53
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:34

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:58

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:53
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '1 Feb 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:34

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:58

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
DataPoint Verified.		17 Apr 2021 17:57:53
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:23:13
User entered '15:41'	(b) (4) Saysamone Banks (b) (4) (b) (4)	01 Feb 2021 23:20:34

US3192345

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:58

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:08:00
User entered '1 Feb 2021 15:41'	System	01 Feb 2021 23:20:34

US3192345

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:34
User closed query 'Per DM CLR: Medical Attention was checked for DAY 8-10 on Diary Dose 1. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' (Site from DM).		21 Apr 2021 11:30:22
Query 'Per DM CLR: Medical Attention was checked for DAY 8-10 on Diary Dose 1. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' answered with 'The AE that correlates with this Diary entry has been updated on EDC and source to reflect yes to medically attended AE. ' (Site from DM).	Saysamone Banks (b) (4) (b) (4)	20 Apr 2021 17:01:16
User opened query 'Per DM CLR: Medical Attention was checked for DAY 8-10 on Diary Dose 1. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 23:47:06
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 16:18:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:12:55
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:31:07

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4)	30 Oct 2020 22:27:50
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 22:01:32
DataPoint Verified.		01 Oct 2020 22:01:23
Reviewed for Safety.		21 Sep 2020 20:26:16
User entered 'USA-US097-2020-mRNA-1273-P301000003'	System	21 Sep 2020 20:26:12
User entered 'New'	(b) (4), (b) (6)	21 Sep 2020 20:26:12

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 19:21:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis acute, LLT: Acute pyelonephritis - version MedDRA\23.0.	Coder Import (b) (4)	21 Nov 2020 00:10:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Nov 2020 00:10:05
	(b) (4)	
Data point term sent to Coder	System	21 Nov 2020 00:09:02
DataPoint Un-verified.	Yvonne De Los Reyes	21 Nov 2020 00:08:13
	(b) (4)	
User entered 'ACUTE PYELONEPHRITIS' reason for change: Data Entry Error	Yvonne De Los Reyes	21 Nov 2020 00:08:13
	(b) (4)	
Data point term sent to Coder	System	21 Nov 2020 00:05:57
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of ACUTE PYELONEPHRITIS and one of UROSEPSIS' (Site from System).	System	21 Nov 2020 00:04:55
Query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of ACUTE PYELONEPHRITIS and one of UROSEPSIS' answered with 'no procedures done, inadvertently checked ' (Site from System).	Yvonne De Los Reyes	21 Nov 2020 00:04:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:27:48
User closed query 'PV Query: The reported event term appears to represent more than one diagnoses within one event term. Please consider splitting the event term into 2 separate SAEs: "Acute pyelonephritis" and "Urosepsis"' (Site from Safety).		12 Oct 2020 15:29:27
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of ACUTE PYELONEPHRITIS and one of UROSEPSIS' (Site from System).	Coder Import (b) (4)	12 Oct 2020 07:02:23
	(b) (4)	
Data point term sent to Coder	System	10 Oct 2020 01:27:55

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	maggie Tono (b) (4)	10 Oct 2020 01:27:24
User entered 'ACUTE PYELONEPHRITIS WITH urosepsis' reason for change: Data Entry Error	maggie Tono (b) (4)	10 Oct 2020 01:27:24
Query 'PV Query: The reported event term appears to represent more than one diagnoses within one event term. Please consider splitting the event term into 2 separate SAEs: "Acute pyelonephritis" and "Urosepsis"' answered with 'has been updated in medical history and source' (Site from Safety).	maggie Tono (b) (4)	10 Oct 2020 01:13:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis acute, LLT: Acute pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 01:10:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 01:10:09
Data point term sent to Coder	System	10 Oct 2020 01:09:53
DataPoint Un-verified.	maggie Tono (b) (4)	10 Oct 2020 01:08:54
Coding entries removed.	maggie Tono (b) (4)	10 Oct 2020 01:08:54
User entered 'ACUTE PYELONEPHRITIS' reason for change: Data Entry Error	maggie Tono (b) (4)	10 Oct 2020 01:08:54
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:01:24
User opened query 'PV Query: The reported event term appears to represent more than one diagnoses within one event term. Please consider splitting the event term into 2 separate SAEs: "Acute pyelonephritis" and "Urosepsis"' (Site from Safety).		30 Sep 2020 11:58:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis acute, LLT: Acute pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 06:33:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 06:33:36
Data point term sent to Coder	System	20 Sep 2020 22:51:00
User entered 'Acute Pyelonephritis with Sepsis'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:01:43
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:01:53
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:02:00
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:34
User entered '27 Aug 2020'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:40
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Sep 2020 22:51:16
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:51:16
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Sep 2020 22:50:52
User entered '15:00'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Sep 2020 22:51:16
User entered '27 Aug 2020 15:00'	System	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:37
User entered '04 Sep 2020'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:43
User entered empty.	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:46
User entered 'Grade 4 (Grade 4)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:47
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:49
User entered '0'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:50
User entered '0'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:52
User entered 'I'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming COVID PCR was negative. Please provide the date of collection and type of testing if known.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:30:17
Query 'PV Query: Thank you for confirming COVID PCR was negative. Please provide the date of collection and type of testing if known.' answered with 'date of collection 28aug2020, collection type nasopharyngeal swab' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 19:18:25
User opened query 'PV Query: Thank you for confirming COVID PCR was negative. Please provide the date of collection and type of testing if known.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:35:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:53
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:30:19
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent via fax' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 19:57:09
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:35:07
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:48:29
User closed query 'IV antibiotic continues until 4Sep2020. Please confirm both discharge date and IV antibiotic end date are correct. Thanks' (Site from CRA).		31 Jan 2021 03:52:41
Query 'IV antibiotic continues until 4Sep2020. Please confirm both discharge date and IV antibiotic end date are correct. Thanks' answered with 'updated' (Site from CRA).	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:21:28
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:21:21
User entered '4 Sep 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:21:21
User opened query 'IV antibiotic continues until 4Sep2020. Please confirm both discharge date and IV antibiotic end date are correct. Thanks' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 19:25:39
DataPoint Verified.		01 Oct 2020 22:03:55

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:57
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:03:58
User entered empty.	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:04:00
User entered '0'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:04:01
User entered '0'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:04:03
User entered '0'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:04:07
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:04:09
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:04:10
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 22:28:30
User closed query 'Per source subject was treated with an IV antibiotic. Please obtain details and update source and RAVE data as needed.' (Site from CRA).		10 Oct 2020 22:49:19
Query 'Per source subject was treated with an IV antibiotic. Please obtain details and update source and RAVE data as needed.' answered with 'iv antibiotics has been updated in con meds ' (Site from CRA).	maggie Tono (b) (4) (b) (4)	10 Oct 2020 01:12:05
User entered '0' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	10 Oct 2020 01:08:54
User opened query 'Per source subject was treated with an IV antibiotic. Please obtain details and update source and RAVE data as needed.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 22:11:04
DataPoint Un-verified.		01 Oct 2020 22:04:19
DataPoint Verified.		01 Oct 2020 22:04:13
User entered '1'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:47
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:04:50
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:04:50
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:28:32
User entered '0'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 23:57:17
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).		23 Nov 2020 12:04:12
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'no procedures done, inadvertently checked ' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:05:03
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:04:50
User entered '0' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:04:50
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:28:33
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).		26 Oct 2020 14:13:27
User entered '1' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	10 Oct 2020 01:08:54
User entered '0'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:11:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:11:12
User entered empty.	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results and date of the CT scan, if known.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:30:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		03 May 2021 16:30:23
Query 'PV Query: Please provide the results and date of the CT scan, if known.' answered with 'records sent via fax ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 19:57:36
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'in records, sent via fax ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 19:57:29
User opened query 'PV Query: Please provide the results and date of the CT scan, if known.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:35:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		16 Apr 2021 07:35:39
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		08 Apr 2021 17:49:10
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		08 Apr 2021 17:47:58

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	08 Apr 2021 17:47:02
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'ONLY IV ANTIBIOTICS WERE GIVEN, AND A CT. CON PROCEDURES PAGE WILL BE UPDATED ' (Site from Safety).	John McGettigan (b) (4)	08 Apr 2021 01:05:06
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'LAB RESULTS WILL GO TO SAFETY' (Site from Safety).	Yvonne De Los Reyes (b) (4)	07 Apr 2021 23:26:44
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'RECORDS OBTAINED, THEY WILL BE SENT OVER TO SAFETY' (Site from Safety).	Yvonne De Los Reyes (b) (4)	07 Apr 2021 23:25:17
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:27:36

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 00:26:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		23 Nov 2020 19:21:39
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).		23 Nov 2020 14:47:16
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		23 Nov 2020 14:47:11
User closed query 'Per DM CLR: SAE Narrative = WAS TREATED WITH IV ANITIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		23 Nov 2020 14:46:59
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'patient reported IV antibiotics, unsure of name. site still awaiting medical records. ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	23 Nov 2020 12:04:27
		21 Nov 2020 00:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[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 'unknown, awaiting medical records' (Site from Safety).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:03:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting medical records to capture for source' (Site from Safety).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:02:46
Query 'Per DM CLR: SAE Narrative = WAS TREATED WITH IV ANITIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'unknown, awaiting medical records ' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:02:18
User opened query 'Per DM CLR: SAE Narrative = WAS TREATED WITH IV ANITIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:58:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		30 Sep 2020 11:57:44
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).		30 Sep 2020 11:57:30
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		30 Sep 2020 11:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 11:56:51
User entered 'Patient reported she was experiencing low back pain, followed by muscle aches and fever. she called the site, PI advised her to go to the ER. she was later diagnosed with a severe kidney infection. Was treated with IV anitibiotics.'	Yvonne De Los Reyes (b) (4)	20 Sep 2020 22:50:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Sep 2020 22:50:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Sep 2020 22:50:52

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
Reviewed for Safety.		23 Nov 2020 14:47:41
User entered 'USA-US097-2020-mRNA-1273-P301000003'		23 Nov 2020 14:47:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Urosepsis, LLT: Urosepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 00:11:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 00:11:04
Data point term sent to Coder	System	21 Nov 2020 00:10:03
User entered 'Urosepsis'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '27 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '04 Sep 2020'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'Grade 4 (Grade 4)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Nov 2020 00:10:19
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Nov 2020 00:09:20
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

US3192345

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	08 Apr 2021 17:37:23
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'HOSPITAL DISCHARGE SUMMARY RECEIVED, IDENTIFIERS WILL BE REDACTED AND WILL BE SENT TO SAFETY' (Site from Safety).	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). DataPoint Verified.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 23:27:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 15:14:14
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:10:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:10:19
User entered '0'	System	21 Nov 2020 00:09:20
	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '28 Aug 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:10:19
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:54
User closed query 'IV antibiotic continues until 4Sep2020. Please confirm both discharge date and IV antibiotic end date are correct. Thanks' (Site from CRA).		31 Jan 2021 03:53:14
Query 'IV antibiotic continues until 4Sep2020. Please confirm both discharge date and IV antibiotic end date are correct. Thanks' answered with 'updated' (Site from CRA).	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:22:41
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:22:34
User entered '04 Sep 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:22:34
User opened query 'IV antibiotic continues until 4Sep2020. Please confirm both discharge date and IV antibiotic end date are correct. Thanks' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 19:25:54
DataPoint Verified.		23 Nov 2020 19:22:36
User entered '02 Sep 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:10:19
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:23:37
User closed query 'PV Query: Please provide the rationale why the causality of Urosepsis with procedure is assessed as Not Applicable.' (Site from Safety).		08 Apr 2021 17:44:35
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
Query 'PV Query: Please provide the rationale why the causality of Urosepsis with procedure is assessed as Not Applicable.' answered with 'CORRECTED ' (Site from Safety).	(b) (4)	
	Yvonne De Los Reyes	07 Apr 2021 23:28:48
	(b) (4)	
DataPoint Un-verified.	Yvonne De Los Reyes	07 Apr 2021 23:28:20
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes	07 Apr 2021 23:28:20
reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the rationale why the causality of Urosepsis with procedure is assessed as Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:27:59
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes	21 Nov 2020 00:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:24:39
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 23:28:20
DataPoint Un-verified.	Yvonne De Los Reyes	07 Apr 2021 23:28:20
User entered '1' reason for change: Data Entry Error	(b) (4)	30 Jan 2021 20:23:44
DataPoint Verified.	maggie Tono (b) (4)	30 Jan 2021 20:23:44
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	23 Nov 2020 19:22:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	21 Nov 2020 00:10:19
User entered '0'	System	21 Nov 2020 00:09:20
	System	21 Nov 2020 00:09:20
	Yvonne De Los Reyes	21 Nov 2020 00:09:20
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:24:41
User closed query 'Per DM CLR: Other Action Take = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).		12 Apr 2021 11:02:08
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'UPDATED ' (Site from DM).	(b) (4)	
	Yvonne De Los Reyes	07 Apr 2021 23:30:05
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes	07 Apr 2021 23:28:20
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 07:40:02
User closed query 'Per medication source no con. meds. are listed with an indication of Urosepsis. Please reconcile. Thanks' (Site from CRA).		31 Jan 2021 03:53:47
Query 'Per medication source no con. meds. are listed with an indication of Urosepsis. Please reconcile. Thanks' answered with 'updated' (Site from CRA).	maggie Tono (b) (4)	30 Jan 2021 20:23:54
DataPoint Un-verified.	(b) (4)	
	maggie Tono (b) (4)	30 Jan 2021 20:23:44
User entered '0' reason for change: Data Entry Error	(b) (4)	
	maggie Tono (b) (4)	30 Jan 2021 20:23:44
User opened query 'Per medication source no con. meds. are listed with an indication of Urosepsis. Please reconcile. Thanks' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:26:42
		23 Nov 2020 19:22:36
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes	21 Nov 2020 00:10:19
	(b) (4)	
User entered '0'	Yvonne De Los Reyes	21 Nov 2020 00:09:20
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:43:09
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).		08 Apr 2021 17:38:28
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		08 Apr 2021 17:38:15
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'WILL SUBMIT WITH DISCHARGE SUMMARY' (Site from Safety).	(b) (4) Yvonne De Los Reyes (b) (4)	07 Apr 2021 23:33:02
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 'COVID PCR WAS NEGATIVE' (Site from Safety).	Yvonne De Los Reyes (b) (4)	07 Apr 2021 23:32:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'CON MED PAGE UPDATED ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	07 Apr 2021 23:30:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:27:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:27:13
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		01 Dec 2020 00:26:55
DataPoint Verified.		23 Nov 2020 19:22:36
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Nov 2020 00:10:19
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Nov 2020 00:10:19
User entered 'PATIENT REPORTED SHE WAS EXPERIENCING LOW BACK PAIN, FOLLOWED BY MUSCLE ACHES AND FEVER. SHE CALLED THE SITE, PI ADVISED HER TO GO TO THE ER. SHE WAS LATER DIAGNOSED WITH A SEVERE KIDNEY INFECTION. WAS TREATED WITH IV ANITIBIOTICS.' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:10:19
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Nov 2020 00:09:20
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Nov 2020 00:09:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 16:48:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Jan 2021 21:18:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 21:18:28
Data point term sent to Coder	System	30 Jan 2021 21:17:35
User entered 'headache'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
User closed query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:08:47
DataPoint Verified.		17 Apr 2021 17:08:22
Query 'Per source this was an medically attended AE. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:01:18
User opened query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:49:01
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
User closed query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:08:51
DataPoint Verified.		17 Apr 2021 17:08:22
Query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:01:22
User opened query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:52:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 08:14:14
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'Updated field since AE is reported in Diary.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:40:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:39:15
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 12:32:33
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 28AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 08:14:16
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 28AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Per query request, the start date of this AE=headache should be 28AUG2020 because that is the initial start date reported in the diary. Field has been updated to reflect the request.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:38:55
User entered '28 Aug 2020' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:38:42
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 28AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 12:32:39
User entered '30 Aug 2020'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
User entered empty.	System	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '02 Sep 2020'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
User entered empty.	System	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:58:43
User closed query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA).		17 Apr 2021 18:58:41
Query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:50:57
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:50:38
User entered 'None (NONE)' reason for change:	Yvonne De Los Reyes	17 Apr 2021 18:50:38
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Apr 2021 17:09:33
User opened query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA).		17 Apr 2021 17:09:30
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) maggie Tono (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'l'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
DataPoint Verified.		17 Apr 2021 17:08:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
User entered '0'	System	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53
User entered '0'	System	30 Jan 2021 21:17:16

US3192345

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:14:53

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 16:49:12
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 21:19:28
Data point term sent to Coder	(b) (4)	
User entered 'fatigue'	System	30 Jan 2021 21:18:36
	maggie Tono (b) (4)	30 Jan 2021 21:18:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
User closed query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:09:39
DataPoint Verified.		17 Apr 2021 17:08:23
Query 'Per source this was an medically attended AE. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:01:30
User opened query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:49:19
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
User closed query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:09:41
DataPoint Verified.		17 Apr 2021 17:08:23
Query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:01:33
User opened query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:53:14
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).		12 Apr 2021 14:55:32
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:05:06
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'Updated field to "yes" per query response.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	07 Apr 2021 00:23:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	07 Apr 2021 00:23:08
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:15:09
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 27AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		12 Apr 2021 14:55:34
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 27AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Changed date because initial start date of fatigue, per dose diary 1, is 27AUG2020.' (Site from DM).	(b) (4)	
User entered '27 Aug 2020' reason for change: Data Entry Error	Crystal Mata (b) (4)	07 Apr 2021 00:25:33
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 27AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4)	
User entered '30 Aug 2020'	Crystal Mata (b) (4)	07 Apr 2021 00:23:08
	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 05:15:15
	maggie Tono (b) (4)	30 Jan 2021 21:18:16
	(b) (4)	

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
User entered empty.	System	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '5 Sep 2020'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
User entered empty.	System	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:58:51
User closed query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA). Query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:51:13
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:51:09
User entered 'None (NONE)' reason for change:	Yvonne De Los Reyes	17 Apr 2021 18:51:09
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Apr 2021 17:09:56
User opened query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA).		17 Apr 2021 17:09:49
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '1' reason for change: Data Entry Error	(b) (4) maggie Tono (b) (4)	18 Mar 2021 23:32:38
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:13:46
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	maggie Tono (b) (4) (b) (4)	18 Mar 2021 23:32:54
' answered with 'updated' (Site from DM).		
User entered '0' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	18 Mar 2021 23:32:38
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	19 Feb 2021 07:40:15
' (Site from DM).		
User entered '1'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
DataPoint Verified.		17 Apr 2021 17:08:23
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
User entered '0'	System	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12
User entered '0'	System	30 Jan 2021 21:18:16

US3192345

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:12

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 16:49:25
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 08:58:40
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 00:43:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 00:43:39
Data point term sent to Coder	System	26 Mar 2021 00:43:07
Coding entries removed.	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:42:15
User entered 'GENERALIZED MUSCLE ACHE' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:42:15
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:41:55
' answered with 'Location of AE is not specified by patient.' (Site from DM).		
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	19 Feb 2021 07:40:23
' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 21:20:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 21:20:28
Data point term sent to Coder	System	30 Jan 2021 21:19:36
User entered 'muscle ache'	maggie Tono (b) (4)	30 Jan 2021 21:19:04
	(b) (4)	

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
User closed query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:10:02
DataPoint Verified.		17 Apr 2021 17:08:27
Query 'Per source this was an medically attended AE. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:02:09
User opened query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:49:33
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
User closed query 'Note, this is a solicited adverse reaction per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection). Please update this field to "YES".' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 02:55:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:59:09
Query 'Note, this is a solicited adverse reaction per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection). Please update this field to "YES".' answered with 'Updated' (Site from DM).	Saysamone Banks (b) (4) (b) (4)	20 Apr 2021 16:37:54
DataPoint Un-verified.	Saysamone Banks (b) (4)	20 Apr 2021 16:37:47
Signature has been broken.	(b) (4) Saysamone Banks (b) (4)	20 Apr 2021 16:37:47
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Saysamone Banks (b) (4)	20 Apr 2021 16:37:47
User opened query 'Note, this is a solicited adverse reaction per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection). Please update this field to "YES".' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 03:20:42
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 16:53:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4)	30 Jan 2021 21:19:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 26AUG2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).		13 Apr 2021 23:20:38
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 26AUG2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'Changed start date per query response, which states that this AE start date did not match the diary initial start date.' (Site from DM).	(b) (4)	
User entered '26 Aug 2020' reason for change: Data Entry Error	Crystal Mata (b) (4)	07 Apr 2021 00:29:34
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 26AUG2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4)	
User entered '30 Aug 2020'	Crystal Mata (b) (4)	07 Apr 2021 00:28:10
	(b) (4)	
	(b) (4), (b) (6)	03 Apr 2021 11:55:08
	maggie Tono (b) (4)	30 Jan 2021 21:19:04
	(b) (4)	

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
User entered empty.	System	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '5 Sep 2020'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
User entered empty.	System	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:58:57
User closed query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA). Query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:10
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:05
User entered 'None (NONE)' reason for change:	Yvonne De Los Reyes	17 Apr 2021 18:52:05
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Apr 2021 17:10:26
User opened query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA).		17 Apr 2021 17:10:10
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'l'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
DataPoint Verified.		17 Apr 2021 17:08:27
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
User entered '0'	System	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58
User entered '0'	System	30 Jan 2021 21:19:04

US3192345

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 16:49:43
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 08:58:48
Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'PATIENT DID NOT SPECIFY LOCATION OF JOINT ACHE. AE IS CORRECT AS IS. THANK YOU.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:43:33
User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 07:40:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 21:21:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 21:21:28
Data point term sent to Coder	System	30 Jan 2021 21:20:37
User entered 'joint ache'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
User closed query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:10:35
DataPoint Verified.		17 Apr 2021 17:08:28
Query 'Per source this was an medically attended AE. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:02:32
User opened query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:49:57
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 16:53:44
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '30 Aug 2020'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
User entered empty.	System	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '1 Sep 2020'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
User entered empty.	System	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:59:05
User closed query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA).		17 Apr 2021 18:59:03
Query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:22
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:18
User entered 'None (NONE)' reason for change:	Yvonne De Los Reyes	17 Apr 2021 18:52:18
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Apr 2021 17:10:47
User opened query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA).		17 Apr 2021 17:10:44
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'l'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
DataPoint Verified.		17 Apr 2021 17:08:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
User entered '0'	System	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18
User entered '0'	System	30 Jan 2021 21:19:58

US3192345

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:18

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 16:50:09
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Jan 2021 21:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 21:22:28
Data point term sent to Coder	System	30 Jan 2021 21:21:37
User entered 'nausea'	maggie Tono (b) (4)	30 Jan 2021 21:20:47
	(b) (4)	

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
User closed query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:11:06
DataPoint Verified.		17 Apr 2021 17:08:30
Query 'Per source this was an medically attended AE. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:02:38
User opened query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:50:07
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
User closed query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:11:08
DataPoint Verified.		17 Apr 2021 17:08:30
Query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:02:42
User opened query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:54:06
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).		12 Apr 2021 14:55:47
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:05:06
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'Updated field to "yes" as this AE is a solicited adverse reaction.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	07 Apr 2021 00:32:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	07 Apr 2021 00:31:45
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:15:37
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 28AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		12 Apr 2021 14:55:49
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 28AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Updated start date to 28AUG2020 to reflect dose diary.' (Site from DM).	(b) (4) Crystal Mata (b) (4)	07 Apr 2021 00:34:23
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 00:31:45
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 28AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:15:46
User entered '30 Aug 2020'	maggie Tono (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
User entered empty.	System	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Jan 2021 21:20:53
User entered 'No (N)' reason for change: Data Entry Error	System	30 Jan 2021 21:20:53
User opened query 'Data is required. Please complete.' (Site from System).	maggie Tono (b) (4)	30 Jan 2021 21:20:53
User entered empty.	(b) (4)	
	System	30 Jan 2021 21:20:47
	maggie Tono (b) (4)	30 Jan 2021 21:20:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '2 Sep 2020'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
User entered empty.	System	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:59:15
User closed query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA). Query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:36
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:31
User entered 'None (NONE)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:31
DataPoint Un-verified.	(b) (4), (b) (6)	17 Apr 2021 17:11:22
User opened query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA). DataPoint Verified.		17 Apr 2021 17:11:18 17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Applicable (NOT APPLICABLE)'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '1' reason for change: Data Entry Error	(b) (4) maggie Tono (b) (4)	18 Mar 2021 23:34:44
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query 'Per CDM: Concomitant Medication checked however it appears that no corresponding concomitant medication is recorded. Kindly review and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 09:29:08
Query 'Per CDM: Concomitant Medication checked however it appears that no corresponding concomitant medication is recorded. Kindly review and update.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	18 Mar 2021 23:35:01
User entered '0' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	18 Mar 2021 23:34:44
User opened query 'Per CDM: Concomitant Medication checked however it appears that no corresponding concomitant medication is recorded. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 21:38:50
User entered '1'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
DataPoint Verified.		17 Apr 2021 17:08:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
User entered '0'	System	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40
User entered '0'	System	30 Jan 2021 21:20:47

US3192345

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:40

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 16:50:22
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Jan 2021 21:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 21:22:28
Data point term sent to Coder	System	30 Jan 2021 21:21:38
User entered 'chills'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
User closed query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:11:28
DataPoint Verified.		17 Apr 2021 17:08:36
Query 'Per source this was an medically attended AE. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:03:00
User opened query 'Per source this was an medically attended AE. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:50:30
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
User closed query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 17:11:41
DataPoint Verified.		17 Apr 2021 17:08:36
Query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' answered with 'Reconciled. ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 17:03:03
User opened query 'Per source this event continues to be documented as NOT an SAR. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 16:54:23
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).		12 Apr 2021 14:56:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:05:06
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'Updated field to "yes" as this is a solicited adverse reaction.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	07 Apr 2021 00:37:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	07 Apr 2021 00:35:19
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:16:01
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom CHILLS on 27AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). User signature succeeded.		12 Apr 2021 14:56:03
	John McGettigan (b) (4)	08 Apr 2021 01:05:06
	(b) (4)	
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom CHILLS on 27AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Updated start date to reflect the dose diary initial start date.' (Site from DM).	Crystal Mata (b) (4)	07 Apr 2021 00:38:03
	(b) (4)	
User entered '27 Aug 2020' reason for change: Data Entry Error	Crystal Mata (b) (4)	07 Apr 2021 00:35:19
	(b) (4)	
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom CHILLS on 27AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:16:09
User entered '30 Aug 2020'	maggie Tono (b) (4)	30 Jan 2021 21:21:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
User entered empty.	System	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '31 Aug 2020'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
User entered empty.	System	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Related (NOT RELATED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:59:23
User closed query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA). Query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:49
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:44
User entered 'None (NONE)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:52:44
User opened query 'This event started after first dose and before second dose making action taken applicable. Please reconcile data.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	17 Apr 2021 17:11:48
DataPoint Verified.		17 Apr 2021 17:11:43
		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '1' reason for change: Data Entry Error	(b) (4) maggie Tono (b) (4)	18 Mar 2021 23:35:33
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User closed query ' Per CDM: Concomitant Medication checked however it appears that no corresponding concomitant medication is recorded. Kindly review and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 09:29:20
Query ' Per CDM: Concomitant Medication checked however it appears that no corresponding concomitant medication is recorded. Kindly review and update.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	18 Mar 2021 23:35:48
User entered '0' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	18 Mar 2021 23:35:33
User opened query ' Per CDM: Concomitant Medication checked however it appears that no corresponding concomitant medication is recorded. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 21:39:40
User entered '1'	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

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Folder: Adverse Events

Form: Adverse Events (8)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

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Folder: Adverse Events

Form: Adverse Events (8)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
DataPoint Verified.		17 Apr 2021 17:08:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:05:06
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
User entered '0'	System	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36
User entered '0'	System	30 Jan 2021 21:21:34

US3192345

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 16:50:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:08:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:08:10
Data point term sent to Coder	System	17 Apr 2021 16:06:59
User entered 'Urinary tract infection'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 16:50:43
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

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Folder: Adverse Events

Form: Adverse Events (9)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '26 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User entered empty.	System	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '02 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User entered empty.	System	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'l'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:07
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User entered '0'	System	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48
User entered 'I'	System	17 Apr 2021 16:06:17

US3192345

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:48

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 16:50:49
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:09:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:09:14
Data point term sent to Coder	System	17 Apr 2021 16:07:59
User entered 'Intractable Nausea'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 16:50:51
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '27 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User entered empty.	System	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '02 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User entered empty.	System	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'l'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User entered '0'	System	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58
User entered 'I'	System	17 Apr 2021 16:07:18

US3192345

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:16:58

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 16:50:58
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:09:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:09:59
Data point term sent to Coder	System	17 Apr 2021 16:09:03
User entered 'Intractable Vomiting'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 16:51:01
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '27 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User entered empty.	System	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '30 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User entered empty.	System	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'l'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:13:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User entered '0'	System	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52
User entered 'I'	System	17 Apr 2021 16:08:23

US3192345

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:17:52

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Bacteraemia, LLT: Bacteremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:12:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:12:08
Data point term sent to Coder	System	17 Apr 2021 16:11:04
User entered 'Bacteremia'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '29 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User entered empty.	System	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '01 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User entered empty.	System	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:59:51
DataPoint Un-verified.		17 Apr 2021 17:19:02
DataPoint Verified.		17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

US3192345

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 18:59:53
User closed query 'Please confirm if a con. med. was taken for Bacteremia. No medication was located on con. med. log with this indication. Thanks' (Site from CRA).		17 Apr 2021 18:59:50
Query 'Please confirm if a con. med. was taken for Bacteremia. No medication was located on con. med. log with this indication. Thanks' answered with 'reconciled in source ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:54:32
DataPoint Un-verified.	(b) (4), (b) (6)	17 Apr 2021 17:19:00
User opened query 'Please confirm if a con. med. was taken for Bacteremia. No medication was located on con. med. log with this indication. Thanks' (Site from CRA).		17 Apr 2021 17:18:57
DataPoint Verified.		17 Apr 2021 17:17:45
User entered 'I'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:45
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User entered '0'	System	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08
User entered '0'	System	17 Apr 2021 16:11:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:08

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 11:03:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 11:03:47
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:17:47
Data point term sent to Coder	System	17 Apr 2021 16:12:04
User entered 'Mild Hyponatremia'	Yvonne De Los Reyes	17 Apr 2021 16:12:04
	(b) (4)	

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Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '29 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User entered empty.	System	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '01 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User entered empty.	System	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'l'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:47
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User entered '0'	System	17 Apr 2021 16:12:04

US3192345

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30
User entered 'I'	System	17 Apr 2021 16:12:04

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:30

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53

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Folder: Adverse Events

Form: Adverse Events (14)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:15:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:15:02
Data point term sent to Coder	System	17 Apr 2021 16:14:05
User entered 'worsening Hypertension'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User entered empty.	System	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '01 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User entered empty.	System	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'l'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:51
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User entered '0'	System	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53
User entered 'I'	System	17 Apr 2021 16:13:30

US3192345

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:18:53

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:16:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:16:03
Data point term sent to Coder	System	17 Apr 2021 16:15:05
User entered 'fever'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '27 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User entered empty.	System	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '29 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User entered empty.	System	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'l'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:17:53
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User entered '0'	System	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29
User entered 'I'	System	17 Apr 2021 16:14:10

US3192345

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:41:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:19:29

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:58

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:34
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
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) (4), (b) (6)	01 Apr 2021 07:19:52
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 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	30 Mar 2021 22:51:39
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)	23 Mar 2021 13:15:48
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site; Headache (General); Day 3, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 21:46:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:58

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 1 Day 6-7, Headache (General) = 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; Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 21:46:10
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site; Headache (General); Day 3, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	maggie Tono (b) (4)	30 Jan 2021 21:22:43
Query 'Per DM CLR: Per Diary Dose 1 Day 6-7, Headache (General) = 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; Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	maggie Tono (b) (4)	30 Jan 2021 20:49:43

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:58

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site; Headache (General); Day 3, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 17:11:19
User opened query 'Per DM CLR: Per Diary Dose 1 Day 6-7, Headache (General) = 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; Nausea/Vomiting (General) = Prevents daily activity requires outpatient IV hydration, however, there is n corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		20 Jan 2021 17:10:48
User closed query 'Per con. med. source subject was given "anitbiotic IV". This medication does not appear in con. med. list in RAVE. Please reconcile. Thanks' (Site from CRA).		15 Jan 2021 05:40:59
Query 'Per con. med. source subject was given "anitbiotic IV". This medication does not appear in con. med. list in RAVE. Please reconcile. Thanks' answered with 'updated' (Site from CRA).	maggie Tono (b) (4) (b) (4)	24 Nov 2020 23:09:04
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:30:08
User opened query 'Per con. med. source subject was given "anitbiotic IV". This medication does not appear in con. med. list in RAVE. Please reconcile. Thanks' (Site from CRA).		30 Oct 2020 22:30:02
User closed query 'Per ETRTR: Please add medication dates and dose for SAE "Acute pyelonephritis with sepsis", thanks.' (Site from CRA).		10 Oct 2020 22:50:12
Query 'Per ETRTR: Please add medication dates and dose for SAE "Acute pyelonephritis with sepsis", thanks.' answered with 'updated ' (Site from CRA).	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:53:37

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please add medication dates and dose for SAE "Acute pyelonephritis with sepsis", thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 21:28:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:41:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
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: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:14:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:14:51
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: ESOMEPRAZOLE SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 14:43:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 14:43:42
Data point term sent to Coder	System	28 Aug 2020 14:43:16
User entered 'Nexium'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'gastroesophageal reflux disease'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '40'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'un Jan 1995'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:20
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 14:42:17

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:43:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:43:43
Data point term sent to Coder	System	28 Aug 2020 14:43:16
User entered 'Losarten/HCTZ'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Hypertension'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '100/25'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'un Sep 2019'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:20:58
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 14:43:04

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 14:45:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 14:45:42
Data point term sent to Coder	System	28 Aug 2020 14:44:20
User entered 'Aspirin'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Cardiac Preventative'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '81'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'once daily (QD)'	Yvonne De Los Reyes	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'un Sep 2019'	Yvonne De Los Reyes	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:21:40
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 14:43:54

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 14:45:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 14:45:43
Data point term sent to Coder	System	28 Aug 2020 14:45:21
User entered 'Vitamin D'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 19:02:29
DataPoint Un-verified.		17 Apr 2021 17:22:28
DataPoint Verified.		17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	(b) (4) Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Vitamin D Deficient'	Yvonne De Los Reyes	28 Aug 2020 14:44:33
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '2000'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'IU (IU)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'un Jan 2015'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '0'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:22:19
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 14:44:33

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Mar 2021 00:43:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 00:43:40
Data point term sent to Coder	System	26 Mar 2021 00:43:07
Coding entries removed.	Crystal Mata (b) (4)	26 Mar 2021 00:42:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Jan 2021 20:46:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 20:46:28
Data point term sent to Coder	System	30 Jan 2021 20:45:31
Coding entries removed.	maggie Tono (b) (4)	30 Jan 2021 20:45:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Sep 2020 13:56:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 13:56:46
Data point term sent to Coder	System	25 Sep 2020 13:56:12
User entered 'Tylenol'	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'FEVER, HEADACHE, GENERALIZED MUSCLE ACHES, JOINT ACHES. PAIN AT INJECTION SITE' reason for change: Data Entry Error	(b) (4) Crystal Mata (b) (4)	26 Mar 2021 00:42:41
User entered 'FEVER, headache, muscle aches, joint aches. pain at injection site' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:45:11
User entered 'Fever'	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:55:29

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '500'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'mg (mg)'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'as needed (PRN)'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Oral (ORAL)'	(b) (4) Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:55:29

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:01:16
User closed query 'Per source start date is 28Aug2020. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 19:01:14
Query 'Per source start date is 28Aug2020. Please reconcile. Thanks' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:12:13
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:12:07
User entered '28 Aug 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:12:07
User opened query 'Per source start date is 28Aug2020. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 17:24:07
DataPoint Un-verified.		17 Apr 2021 17:23:45
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:20:33
User entered '30 Aug 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:25:27
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 13:56:29
User entered '21 Sep 2020' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:56:29
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 13:55:29
User entered empty.	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:55:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '0'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	maggie Tono (b) (4)	30 Jan 2021 21:25:27
	(b) (4)	
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:01:21
User closed query 'Per source end date is 02Sep2020. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 19:01:19
Query 'Per source end date is 02Sep2020. Please reconcile. Thanks' answered with 'updated' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:12:18
Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:12:07
User entered '02 Sep 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:12:07
User opened query 'Per source end date is 02Sep2020. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 17:24:35
DataPoint Un-verified.		17 Apr 2021 17:24:10
DataPoint Verified.		17 Apr 2021 17:23:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:20:33
User entered '05 Sep 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Jan 2021 21:25:27
User entered empty.	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:55:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
DataPoint Verified.		17 Apr 2021 17:23:38
User closed query 'Per DM CLR - RQ: Site's response noted. However, these eDiary symptoms persist more than 7 days post vaccination and this was an AE reporting criteria per Protocol section 8.3.4. Review and update this field to "Yes". Otherwise, clarify.' (Site from DM).		14 Apr 2021 06:23:18
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
Query 'Per DM CLR - RQ: Site's response noted. However, these eDiary symptoms persist more than 7 days post vaccination and this was an AE reporting criteria per Protocol section 8.3.4. Review and update this field to "Yes". Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4) Saysamone Banks (b) (4)	06 Apr 2021 18:07:50
User entered 'Yes (Y)' reason for change: Per Query Resolution	Saysamone Banks (b) (4)	06 Apr 2021 18:06:26
User opened query 'Per DM CLR - RQ: Site's response noted. However, these eDiary symptoms persist more than 7 days post vaccination and this was an AE reporting criteria per Protocol section 8.3.4. Review and update this field to "Yes". Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Apr 2021 11:54:54
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).		23 Nov 2020 05:48:59
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'patient did not meet ae criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	28 Oct 2020 22:35:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 07:44:34
User entered 'No (N)'	Norma Barrientos (b) (4)	25 Sep 2020 13:55:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
User entered empty.	System	25 Sep 2020 13:55:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
User entered empty.	System	25 Sep 2020 13:55:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:22
User entered empty.	System	25 Sep 2020 13:55:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:26:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:26:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:20:33
Data point term sent to Coder Coding entries removed.	System Crystal Mata (b) (4) (b) (4)	26 Mar 2021 00:43:07 26 Mar 2021 00:42:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Jan 2021 20:50:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Jan 2021 20:50:47
Data point term sent to Coder Coding entries removed.	System maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:45:31 30 Jan 2021 20:45:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:56:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	25 Sep 2020 13:56:46
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	25 Sep 2020 13:56:11
User entered 'Ibuprofen'	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'FEVER, HEADACHE, GENERALIZED MUSCLE ACHES, JOINT ACHES. PAIN AT INJECTION SITE' reason for change: Data Entry Error	(b) (4) Crystal Mata (b) (4)	26 Mar 2021 00:42:53
User entered 'FEVER, headache, muscle aches, joint aches. pain at injection site' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Jan 2021 20:45:21
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:56:16
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' answered with 'patient did not meet ae criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	28 Oct 2020 22:36:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 07:44:02
User entered 'Fever'	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '800'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'mg (mg)'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'as needed (PRN)'	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'Oral (ORAL)'	(b) (4) Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 19:01:42
User closed query 'Source does not specify a date for this field. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 19:01:31
Query 'Source does not specify a date for this field. Please reconcile. Thanks' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:37:38
User opened query 'Source does not specify a date for this field. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 17:27:25
DataPoint Un-verified.		17 Apr 2021 17:26:45
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '21 Sep 2020'	(b) (4) Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '0'	(b) (4) Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	maggie Tono (b) (4)	30 Jan 2021 21:24:33
	(b) (4)	
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
DataPoint Verified.		17 Apr 2021 19:01:46
User closed query 'Source does not specify a date for this field. Please reconcile. Thanks' (Site from CRA).		17 Apr 2021 19:01:43
Query 'Source does not specify a date for this field. Please reconcile. Thanks' answered with 'Reconciled.' (Site from CRA).	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:37:48
User opened query 'Source does not specify a date for this field. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 17:27:30
DataPoint Un-verified.		17 Apr 2021 17:26:46
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4) maggie Tono (b) (4)	30 Jan 2021 21:24:33
User entered empty.	(b) (4) Norma Barrientos (b) (4)	25 Sep 2020 13:56:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
User closed query 'Per source (indication field) this medication was taken for a solicited event. Please reconcile. Thanks' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 19:02:06 17 Apr 2021 19:01:49
Query 'Per source (indication field) this medication was taken for a solicited event. Please reconcile. Thanks' answered with 'updated' (Site from CRA). Signature has been broken.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 18:40:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes	17 Apr 2021 18:40:03
User opened query 'Per source (indication field) this medication was taken for a solicited event. Please reconcile. Thanks' (Site from CRA). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:28:01 17 Apr 2021 17:26:49
DataPoint Verified.		17 Apr 2021 17:26:35
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:49:11
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'patient did not meet ae criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	28 Oct 2020 22:36:24
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 07:44:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
User entered empty.	System	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
User entered empty.	System	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:24
User entered empty.	System	25 Sep 2020 13:56:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User closed query 'Per DM CLR: Please provide the specific name (generic or brand) of IV antibiotic if known. Update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please provide the specific name (generic or brand) of IV antibiotic if known. Update as appropriate.' answered with 'patient did not specify what the name is and also it is not noted in the notes ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 03:44:24
User opened query 'Per DM CLR: Please provide the specific name (generic or brand) of IV antibiotic if known. Update as appropriate.' (Site from DM).	maggie Tono (b) (4)	29 Jan 2021 23:41:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIBIOTICS, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\\202003.	(b) (4)	
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 12:15:44
DataPoint Verified.	(b) (4)	
Data point term sent to Coder	(b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'IV Antibiotic'	System	12 Nov 2020 21:30:14
	Amanda Hermosillo	12 Nov 2020 21:29:52
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'No (N)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'Acute pyelonephritis'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'UNK'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'mg (mg)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered empty.	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
DataPoint Verified.		17 Apr 2021 17:28:48
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	11 Dec 2020 02:43:28
User entered 'once daily (QD)' reason for change:	System	11 Dec 2020 02:43:28
Data Entry Error	Crystal Mata (b) (4)	11 Dec 2020 02:43:07
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	11 Dec 2020 02:43:07
User entered 'once (ONCE)' reason for change: Data Entry Error	Crystal Mata (b) (4)	11 Dec 2020 02:43:07
DataPoint Verified.	(b) (4)	
User entered 'other (OTHER)'	(b) (4), (b) (6)	23 Nov 2020 19:27:49
	Amanda Hermosillo	12 Nov 2020 21:29:52
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
DataPoint Verified.		17 Apr 2021 17:28:48
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
User closed query 'Per CDM: Please verify and update if this can be one of the available option in the frequency field (Once) else clarify. Please update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:30:14
Query 'Per CDM: Please verify and update if this can be one of the available option in the frequency field (Once) else clarify. Please update as appropriate. Thank you.' answered with 'UPDATED FREQUENCY. THANK YOU.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	11 Dec 2020 02:45:33
DataPoint Un-verified.	Crystal Mata (b) (4) (b) (4)	11 Dec 2020 02:43:07
User entered empty; reason for change Data Entry Error	Crystal Mata (b) (4) (b) (4)	11 Dec 2020 02:43:07
User opened query 'Per CDM: Please verify and update if this can be one of the available option in the frequency field (Once) else clarify. Please update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 03:35:32
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'Once'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'Intravenous (INTRAVENOUS)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered empty.	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered '28 Aug 2020'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered '0'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'No (N)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered '04 Sep 2020'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:20:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:27:49
User entered 'No (N)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User entered '1'	System	11 Dec 2020 02:43:28
User entered empty.	System	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User entered '1'	System	11 Dec 2020 02:43:28
User entered empty.	System	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:26
User entered '804 (804)'	System	11 Dec 2020 02:43:28
User entered empty.	System	12 Nov 2020 21:29:52

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN, PRODUCTSYNONYM: CIPRO [CIPROFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 15:56:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 15:56:07
Data point term sent to Coder	System	17 Apr 2021 15:54:54
User entered 'Cipro'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered 'Pyelonephritis'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered '500'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered 'twice daily (BID)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered '02 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered '09 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User entered '2'	System	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User entered '1'	System	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:30
User entered '804 (804)'	System	17 Apr 2021 15:54:24

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 15:57:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 15:57:07
Data point term sent to Coder	System	17 Apr 2021 15:55:55
User entered 'lasix'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered 'Fluid retention'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered '40'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered '01 Sep 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:20
User entered '02 Sep 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	17 Apr 2021 15:55:20
User entered '02 Sep 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:20
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	17 Apr 2021 15:55:02
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:29:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User entered '1'	System	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User entered '1'	System	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:37
User entered '804 (804)'	System	17 Apr 2021 15:55:02

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 08:09:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 08:09:34
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:30:34
Data point term sent to Coder	System	17 Apr 2021 15:56:55
User entered 'Toradol'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered 'pain'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered '15'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered 'Intravenous (INTRAVENOUS)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:30:34
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User entered empty.	System	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User entered empty.	System	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:43:41
User entered empty.	System	17 Apr 2021 15:56:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 15:59:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 15:59:08
Data point term sent to Coder	System	17 Apr 2021 15:57:56
User entered 'Robaxin'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered 'Body aches'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered '500'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User entered empty.	System	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User entered empty.	System	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:16
User entered empty.	System	17 Apr 2021 15:57:48

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
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)	19 Apr 2021 08:06:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 08:06:26
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:31:32
Data point term sent to Coder	System	17 Apr 2021 15:58:56
User entered 'Zofran'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered 'intractable Nausea/Vomiting'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered '4'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered 'Intravenous (INTRAVENOUS)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:31:32
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User entered empty.	System	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User entered empty.	System	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:17
User entered empty.	System	17 Apr 2021 15:58:36

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:57:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:57:50
Data point term sent to Coder Coding entries removed.	System	19 Apr 2021 22:25:06
	Saysamone Banks (b) (4)	19 Apr 2021 22:24:20
DataPoint Verified.	(b) (4)	17 Apr 2021 17:32:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Apr 2021 16:01:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Apr 2021 16:01:08
Data point term sent to Coder	System	17 Apr 2021 15:59:57
User entered 'Rocephin'	Yvonne De Los Reyes	17 Apr 2021 15:59:25
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
DataPoint Verified.		21 Apr 2021 00:00:17
User closed query 'Per source Rocephin was also taken for 'Bacteremia'. Please reconcile. Thanks' (Site from CRA).		21 Apr 2021 00:00:12
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
Query 'Per source Rocephin was also taken for 'Bacteremia'. Please reconcile. Thanks' answered with 'Updated' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Saysamone Banks (b) (4)	19 Apr 2021 22:24:27
	(b) (4)	
	Saysamone Banks (b) (4)	19 Apr 2021 22:24:20
	(b) (4)	
User entered 'URINARY TRACT INFECTION/bacteremia' reason for change: Data Entry Error	Saysamone Banks (b) (4)	19 Apr 2021 22:24:20
	(b) (4)	
User opened query 'Per source Rocephin was also taken for 'Bacteremia'. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	17 Apr 2021 19:00:36
DataPoint Verified.		17 Apr 2021 17:32:13
User entered 'Urinary tract infection'	Yvonne De Los Reyes	17 Apr 2021 15:59:25
	(b) (4)	

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered 'I'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered 'g (g)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered 'Intravenous (INTRAVENOUS)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User entered empty.	System	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User entered empty.	System	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:20
User entered empty.	System	17 Apr 2021 15:59:25

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
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) (b) (4)	17 Apr 2021 16:02:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 16:02:02
Data point term sent to Coder	System	17 Apr 2021 16:00:57
User entered 'Acetaminophen'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered 'Fever'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered '650'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered empty.	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered '0'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User signature succeeded.	John McGettigan (b) (4)	20 Apr 2021 13:43:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 17:32:37
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User entered empty.	System	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User entered empty.	System	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:24
User entered empty.	System	17 Apr 2021 16:00:07

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:41:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:34
DataPoint Verified.		17 Apr 2021 17:37:49
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
Signature has been broken.	(b) (4)	
	Yvonne De Los Reyes	16 Apr 2021 22:28:43
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes	16 Apr 2021 22:28:43
	(b) (4)	
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes	28 Aug 2020 14:47:59
	(b) (4)	
User entered 'Yes (Y)'	Yvonne De Los Reyes	28 Aug 2020 14:47:04
	(b) (4)	

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered '28 Aug 2020'	Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:29:35

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered 'Chest x-ray'	Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:29:35

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:29:35

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:29:35

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:45
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered '28 Aug 2020'	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:02

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:45
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered 'CT abdomen & pelvis with contrast'	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:02

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:45
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:02

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:45
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered empty.	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:02

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:50
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered '28 Aug 2020'	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:12

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:50
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered 'EKG'	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:12

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:50
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:12

US3192345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:50
DataPoint Verified.		17 Apr 2021 17:40:55
User signature succeeded.	John McGettigan (b) (4)	17 Apr 2021 13:26:23
User entered empty.	(b) (4) Yvonne De Los Reyes (b) (4)	16 Apr 2021 22:30:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:35:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'USA-US097-2020-MRNA-1273-P301000003'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	01 Oct 2020 22:15:47
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:49
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:51
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:53
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:57
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:59
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:01
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'John'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:03
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'McGettigan'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:05
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '5390 E. Erickson Drive'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:06
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Tucson'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:08
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'AZ'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:09
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '85712'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:31:13
DataPoint Verified.		01 Oct 2020 22:16:11
User entered 'US'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 17:54:12
User entered '4'	System	01 Feb 2021 13:43:48
User entered '3'	System	23 Nov 2020 14:48:23
User entered '2'	System	12 Oct 2020 15:31:21
User entered '1'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:35:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'USA-US097-2020-MRNA-1273-P301000003'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:47
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:49
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:51
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:53
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:57
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:59
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:01
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'John'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:03
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'McGettigan'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:05
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '5390 E. Erickson Drive'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:06
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Tucson'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:08
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'AZ'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:09
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '85712'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (v) (4), (b) (6)	12 Oct 2020 15:31:13
DataPoint Verified.		01 Oct 2020 22:16:11
User entered 'US'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 17:54:12
User entered '4'	System	01 Feb 2021 13:43:48
User entered '3'	System	23 Nov 2020 14:48:23
User entered '2'	System	12 Oct 2020 15:31:21
User entered '1'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered '21/Sep/2020 16:26'	(b) (4) System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:31:13
User entered 'I'		21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:35:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'USA-US097-2020-MRNA-1273-P301000003'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:47
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:49
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:51
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:53
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	01 Oct 2020 22:15:57
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:59
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:01
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'John'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:03
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'McGettigan'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:05
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '5390 E. Erickson Drive'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:06
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Tucson'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:08
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'AZ'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:09
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '85712'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:31:13
DataPoint Verified.		01 Oct 2020 22:16:11
User entered 'US'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 17:54:12
User entered '4'	System	01 Feb 2021 13:43:48
User entered '3'	System	23 Nov 2020 14:48:23
User entered '2'	System	12 Oct 2020 15:31:21
User entered '1'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered '12/Oct/2020 11:31'	(b) (4) System	12 Oct 2020 15:31:21

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:48:08
User entered 'I'		12 Oct 2020 15:31:21

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:35:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'USA-US097-2020-MRNA-1273-P301000003'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:47
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:49
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:51
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:53
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:57
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:59
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:01
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'John'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:03
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'McGettigan'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:05
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '5390 E. Erickson Drive'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:06
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Tucson'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:08
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'AZ'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:09
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '85712'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	12 Oct 2020 15:31:13
DataPoint Verified.		01 Oct 2020 22:16:11
User entered 'US'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 17:54:12
User entered '4'	System	01 Feb 2021 13:43:48
User entered '3'	System	23 Nov 2020 14:48:23
User entered '2'	System	12 Oct 2020 15:31:21
User entered '1'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered '23/Nov/2020 14:48'	(b) (4) System	23 Nov 2020 14:48:23

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:43:37
User entered 'I'		23 Nov 2020 14:48:23

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:35:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'USA-US097-2020-MRNA-1273-P301000003'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:47
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:49
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:51
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:53
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:57
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:59
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:01
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'John'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:03
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'McGettigan'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:05
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '5390 E. Erickson Drive'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:06
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Tucson'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:08
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'AZ'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:09
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '85712'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:31:13
DataPoint Verified.		01 Oct 2020 22:16:11
User entered 'US'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 17:54:12
User entered '4'	System	01 Feb 2021 13:43:48
User entered '3'	System	23 Nov 2020 14:48:23
User entered '2'	System	12 Oct 2020 15:31:21
User entered '1'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:41:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered '01/Feb/2021 08:43'	(b) (4) System	01 Feb 2021 13:43:48

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:41:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:43:48

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:35:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'USA-US097-2020-MRNA-1273-P301000003'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:47
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:49
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:51
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:53
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Yes (Y)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	01 Oct 2020 22:15:56
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:57
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:15:59
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'No (N)'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:01
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'John'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:03
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'McGettigan'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:05
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '5390 E. Erickson Drive'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:06
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'Tucson'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:08
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered 'AZ'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:16:09
Reviewed for Safety.		21 Sep 2020 20:26:34
User entered '85712'	System	21 Sep 2020 20:26:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:52:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:31:13
DataPoint Verified.		01 Oct 2020 22:16:11
User entered 'US'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 17:54:12
User entered '4'	System	01 Feb 2021 13:43:48
User entered '3'	System	23 Nov 2020 14:48:23
User entered '2'	System	12 Oct 2020 15:31:21
User entered '1'	System	21 Sep 2020 20:26:40

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:41:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:44:44
User entered '08/Apr/2021 10:54'	(b) (4) System	08 Apr 2021 17:54:12

US3192345

Folder: SAE USA-US097-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:41:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:22:48
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:44:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:54:12